
From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 4/16/2018 12:11:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Bruff, Susan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3bdf8cac94049dcab28d2eb5fad5137-bruffs]
Subject: RE: Exec Sec FYI: KEI and patent reporting

Mark and Susan:

Is this ExSec request for the University of Pennsylvania and Juxtapid? Or is this for another KEI request?

Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, April 13, 2018 10:38 AM
To: Bruff, Susan (NIH/OD) [E] <bruffs@od.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Exec Sec FYI: KEI and patent reporting

I know you have seen this correspondence but just wanted to share what I received from the ExSec record and assignment.

Work Folder Information
Work Folder: WF 371552
Process: FYI
Program Analyst: Crone, Colleen (NIH/OD) [E]
Due Date:
WF Subject: OS forwards for direct reply letter from James Love from Knowledge Ecology International (KEI) requesting investigation of and remedy to non-disclosure of NIH funding for 5 patents.
IC: od_osp
From: Love, James
To: Azar, Alex
Remarks: Assigned to OTT to create a draft direct reply to James Love on behalf of the Secretary for OD clearance. Please forward draft to Exec. Sec. to obtain clearances before mailing out. DUE: 04/17/18 COB. Also forwarded as FYI to NINDS, OIR, OM, OMA, OGC, OCPL, OLPA, and OSP.

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 4/10/2018 10:43:43 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonld]
CC: Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Jackson, Stephanie (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a0dc9ddbc4fa2be8ca6ea23d081ca-jacksonsg]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Mullman, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=084e30198ca04156b3c91537de14adb3-mullmanl]
Subject: RE: Exondys 51 patents

Also – this request was sent to the Secretary. While OPERA is looking into the request, we have not heard whether the Secretary has delegated a response to NIH. The requestors, in addition to asking HHS to take title, has requested a meeting with the Secretary.

Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, April 09, 2018 6:17 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Mullman, Lauren (NIH/OD) [E] <lauren.mullman@nih.gov>
Subject: RE: Exondys 51 patents

Thank you. I was talking to Laura. **b5** These comments are useful background if he chooses to go into more detail.

From: Hammersla, Ann (NIH/OD) [E]
Sent: Monday, April 09, 2018 4:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Mullman, Lauren (NIH/OD) [E] <lauren.mullman@nih.gov>
Subject: FW: Exondys 51 patents

All: Thank you Mark for your offer to help. The following is OPERA's information for the steps of review and options available.

b5

b5

Ann

From: Hammersla, Ann (NIH/OD) [E]
Sent: Monday, April 09, 2018 11:04 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Mullman, Lauren (NIH/OD) [E] <lauren.mullman@nih.gov>
Subject: RE: Exondys 51 patents

Mark: A little more information may be helpful. I have drafted and it is being reviewed. When ok'd I will send to you for your review.

Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, April 06, 2018 3:51 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Mullman, Lauren (NIH/OD) [E] <lauren.mullman@nih.gov>
Subject: RE: Exondys 51 patents

b5

Ann: can we work on this together? Not sure if you to say more about OER's steps and processes.

From: Berkson, Laura (NIH/OD) [E]
Sent: Friday, April 06, 2018 3:07 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Mullman, Lauren (NIH/OD) [E] <lauren.mullman@nih.gov>
Subject: RE: Exondys 51 patents

Hi Mark,

Thanks for flagging this. Dr. Collins is testifying in front of the House Appropriations L-HHS Subcommittee on Wednesday, April 11 and we want to make sure he is prepared in case this comes up. Can you help pull together some talking points? We would need something by Monday afternoon. I'm hoping we can pull from previous march-in bullets. NINDS pulled together some background bullets (see below), but I think we need something that would be responsive to a question. I've taken a first stab at drafting a mock question and left a spot for a response. Feel free to make edits to that or the NINDS background.

Happy to chat if that would be helpful.

Laura

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, April 04, 2018 5:19 PM
To: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Baker, Rebecca (NIH/OD) [E] <rebecca.baker@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: FW: Exondys 51 patents

KEI, Health GAP, Patients for Affordable Drugs, People of Faith for Access to Medicines, Social Security Works, and Universities Allied for Essential Inventions sent Ann Hammersla a copy of a letter they plan to send to Secy Azar

tomorrow (cc'ing Daniel Levinson HHS OIG) asserting that inventors/institutions failed to disclose NIH funding on 5 relevant patents on Serapta's Exondys 51 (eteplirsen), a treatment for DMD, "which provides the government with an opportunity to take title to patents, and to use the ownership of the patents as leverage to lower the price." KEI also suggests that "the NIH and the U.S. Department of Defense review 91 other patents
assigned to Sarepta which do not disclose federal research funding." He asks for a meeting with the HHS.

From: Hammersla, Ann (NIH/OD) [E]
Sent: Wednesday, April 04, 2018 3:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Exondys 51 patents

FYI

From: James Love <james.love@keionline.org>
Sent: Wednesday, April 04, 2018 1:08 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Andrew S. Goldman <andrew.goldman@keionline.org>; Kim Treanor <kim.treanor@keionline.org>
Subject: Exondys 51 patents

Dear Ann Hammersla,

I am attaching two PDF files that we are sending tomorrow, regarding the patents on Exondys 51, so you have a heads up.

Jamie

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

---

From: Joe Allen [jallen@allen-assoc.com]
Sent: 4/5/2017 2:10:34 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Rep. Doggett's press release on letter to Pres Trump on using march in rights to control drug prices

FYI:

(https://doggett.house.gov/media-center/press-releases/congressional-democrats-trump-we-re-calling-your-hand-lower-prescription)

Congressional Democrats to Trump: "We're Calling Your Hand -- Lower Prescription Drug Prices"

April 4, 2017

Washington, D.C.—Today, 51 members of Congress, led by U.S. Congressman Lloyd Doggett (D-TX), urged President Donald Trump to fulfill his oft-repeated promise to lower prescription drug prices. Rep. Doggett and his colleagues asked President Trump to protect public access to drugs developed with public dollars. Rep. Doggett, a senior member of the Ways and Means Committee and a leader of the House Prescription Drug Task Force, said:

> "Today, we are calling Trump's hand on his promises to lower prescription drug prices. To date he has failed completely to fulfill his commitment. So far his only related legislative action was to endorse a $28.5 billion tax windfall for brand name drug makers, while seeking nothing in return for consumers. He can act immediately to discourage many drug makers from charging the public sky-high prices on drugs developed with public dollars.
>
> "When taxpayers finance pharmaceutical research, they have earned the right to obtain affordable access to that medication. And that is not happening now. Instead, taxpayers are hit twice for too many drugs—once when they pay for drug research and again when the pharmaceutical company engages in price gouging. When drug makers are granted unrestricted, government-approved monopolies and exploit them to set monopoly prices, a diagnosis of a dread disease can become a prognosis for financial ruin."

The letter explains that federal agencies, like the National Institutes of Health (NIH), can foster competition by requiring companies holding patents for publicly-funded inventions to license the patent to third parties. This authority was created by the Bayh-Dole Act, a 1980 statute, and can be used when "action is necessary to alleviate health and safety needs which are not being reasonably satisfied" or when the benefits of the taxpayer-funded drug are not "available to the public on reasonable terms." This effort is supported by Public Citizen, Doctors for America, Consumers Union, and Knowledge Ecology International. The Prescription Drug Task Force aims to advance legislative and administrative solutions to lower the cost of prescription medications for American families.

--

Joseph P. Allen
President
Allen and Associates
60704 Rt. 26, South
Bethesda, OH 43719
(W) 740-484-1814
(c) b6
www.allen-assoc.com

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/27/2019 1:59:17 PM
To: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Goldstein, Bruce (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]
Subject: Re: Emailing: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf, NIHtoKEI re MTTI 25Aug2019.docx

Ok, I'll simplify.

From: "Berkley, Dale (NIH/OD) [E]" <berkleyd@od.nih.gov>
Date: Monday, August 26, 2019 at 16:23:16
To: "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Cc: "Goldstein, Bruce (NIH/OD) [E]" <goldsteb@mail.nih.gov>, "Pazman, Cecilia (NIH/NHLBI) [E]" <pazmance@nhlbi.nih.gov>
Subject: RE: Emailing: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf, NIHtoKEI re MTTI 25Aug2019.docx

I understand b5
b5

-----Original Message-----
From: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Sent: Monday, August 26, 2019 4:03 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Pazman, Cecilia (NIH/NHLBI) [E] <pazmance@nhlbi.nih.gov>
Subject: RE: Emailing: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf, NIHtoKEI re MTTI 25Aug2019.docx
Importance: High

Their listed of comments were essentially the same as before.
b5

-----Original Message-----
From: Berkley, Dale (NIH/OD) [E]
Sent: Monday, August 26, 2019 15:57
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Pazman, Cecilia (NIH/NHLBI) [E] <pazmance@nhlbi.nih.gov>
Subject: RE: Emailing: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf, NIHtoKEI re MTTI 25Aug2019.docx

Misha:

I don't see any objections or even any questions from KEI in their August 23 letter that you attached. Have I missed any?

b5

Best, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch Bldg. 31, Rm. 47 Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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-----Original Message-----
From: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Sent: Sunday, August 25, 2019 7:47 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Pazman, Cecilia (NIH/NHLBI) [E] <pazmance@nhlbi.nih.gov>
Subject: Emailing: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf, NIHtoKEI re MTTI 25Aug2019.docx

Dale and Mark -- a pdf with KEI's comments (received Aug 23) and a word doc with my response enclosed. Please have a look at both and let me know if you have any comments or edits to the response.

Thanks again!

Regards,

Michael A. Shmilovich, Esq., CLP

Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@mail.nih.gov

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“Always be yourself….unless you can be a pyrate… then; obviously, be a pyrate”

Your message is ready to be sent with the following file or link attachments:

KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf NIHtoKEI re MTTI 25Aug2019.docx

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 8/27/2019 2:29:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

Ok thanks.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, August 27, 2019 10:28 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: Re: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

I saw your response to Misha and will work with jim in a similar vein

Sent from my iPhone

On Aug 27, 2019, at 10:22 AM, Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov> wrote:

> More and more questions. b5
> b5
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Knabb, Jim (NIH/NCI) [E]" <jim.knabb@nih.gov>
> > **Date:** August 27, 2019 at 8:57:25 AM EDT
> > **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
> > **Subject: FW: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies**
> >
> > Hi Mark,
> >
> > I hope you are doing well. I see that you're out of the office, I hope you're enjoying a vacation.
> >
> > Could we work together to craft a response to KEI regarding their comments below? My understanding from Richard is b5
> > b5

Thanks,
Jim

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, August 23, 2019 4:57 PM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Questions Regarding NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

Dear Dr. Knabb:

We are writing to request information about the proposed exclusive license in CAR therapies targeting certain B-cell cancers, which was noticed at 84 FR 43148, to Lyell Immunopharma, Inc. ("Lyell"), located in South San Francisco, CA.

1. According to the notice, there are two inventions covered by the proposed license, described at OTT Ref. Nos. E-016-2015 and E-017-2017.
    a. What clinical trials are associated with the subject inventions? We are aware of only one trial, NCT01593696, which is associated with E-016-2015.
    b. Can you please confirm that this trial is associated with the licensed technology?
    c. How much will the NIH contribute to the cost of NCT01593696? A research on the NIH RePORTER database for NCT01593696 for all fiscal years returned zero results.
    d. Are there any other clinical trials are associated with these technologies? If so, what NIH grant numbers, if any, associated with each trial, and how much did each trial cost?

2. Please confirm the stages of research and development that has been completed or started for each invention.

3. What is the NIH's rationale for concluding that an exclusive, rather than a non-exclusive, or a partially-exclusive license is a necessary incentive under 35 U.S.C. § 209?
a. Did the NIH estimate the amount of investment required to bring the technology to practical application?
b. Did the NIH consider the incentives from the Orphan Drug Act regulatory exclusivity for rare diseases or FDA rules on exclusive rights to rely on regulatory test data as inadequate to protect the private investment in the technology?

4. What is the period of exclusivity for the proposed exclusive license?
a. NIH's model exclusive license, located at https://www.ott.nih.gov/resources#MLA, does include duration as a standard term. As a general matter, does the NIH negotiate the period of exclusivity for proposed licenses?
b. If the NIH does not negotiate duration as a term of its licenses, why not? How is this consistent with 35 U.S.C. § 209?

c. CAR technologies are promising new cancer treatments, yet costs hundreds of thousands of dollars, straining hospital budgets and threatening patient access. From the industry perspective, they can be highly lucrative technologies. Has the NIH undertaken an economic analysis to determine if a shorter exclusivity period such as a five or 10 year term would be a sufficient incentive under 35 U.S.C. § 209 for the licensed technologies?

5. The proposed territorial application of the license is "worldwide." NIH's licensing page, https://www.ott.nih.gov/licensing, states that "***[w]here appropriate***, licenses ***can*** be granted on a worldwide basis."(Emphasis added). Determining the territorial application of a license on a case-by-case basis would comport with 35 U.S.C. § 209. Yet, KEI rarely encounters a licensing notice where the proposed field of use is not worldwide.
a. Did the NIH consider any of the benefits of licensing the technology on an exclusive basis in some but not all countries?

6. What are the proposed royalties and other terms of financial compensation for this proposed exclusive license?
a. What licensing guidelines, if any, does the NIH Office of Technology Transfer use to determine royalty rates for its licenses?
b. What are the average royalty rates for licenses in NIH-owned CAR therapies, as well as the average royalty rates for NIH license for cancer therapeutics.

7. How has the NIH, through the proposed license, sought to give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries"? How has the NIH contemplated how its licensing decisions affect access to CAR therapies in developing countries?
a. If the license is worldwide, how will the NIH ensure access in countries with lower incomes, given the lack of access to other CAR T treatments in developing countries?

8. Has the NIH sought the advice of the Attorney General under 40 U.S.C. § 559?

Thank you in advance for your consideration of these questions.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Buchbinder, Barry (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=BBUCHBINDER]
Sent: 3/16/2017 2:28:50 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: ACTION - Fwd: Anyone have objection from KEI in 2017

Mark,

As an excuse to write you .... :-)

KEI lists their activities on their home page (<http://www.keionline.org/>, scroll down). A quick look ("quick" => I might have missed something) found nothing in 2017 stood out as relevant. Note that Zika is listed <http://keionline.org/zika>, so it seems to be pretty up to date.

Hope you're having fun!

- Barry
TTIPO/NIAID/NIH ◈ 240-627-3678 / Fax: 240-627-3117 / Office: 5601/6D16 • 301-496-2644 /
https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0010146018

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From: Buchbinder, Barry (NIH/NIAID) [E]
Sent: Thursday, March 16, 2017 10:00 AM
To: Salata, Carol (NIH/NIAID) [E] <CSalata@niaid.nih.gov>; Castiblanco, Diana (NIH/NIAID) [C] <diana.castiblanco@nih.gov>; Contreras, Vince (NIH/NIAID) [E] <vince.contreras@nih.gov>; Petrik, Amy (NIH/NIAID) [E] <petrika@niaid.nih.gov>
Subject: RE: ACTION - Fwd: Anyone have objection from KEI in 2017

Carol, I'm not aware of any objections.

All:

To save you looking for who this is (like I had to), KEI = Knowledge Ecology International (<http://www.keionline.org/>; <https://en.wikipedia.org/wiki/Knowledge_Ecology_International>), Jamie Love's group.

In case you want to look at it, the objection and related items seem to be here <http://keionline.org/zika>.

Also, KEI lists their activities on their home page (scroll down) – nothing in 2017 stood out as relevant.

Best,

- Barry
TTIPO/NIAID/NIH ◈ 240-627-3678 / Fax: 240-627-3117 / Office: 5601/6D16 • 301-496-2644 /
https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0010146018

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From: Salata, Carol (NIH/NIAID) [E]
Sent: Thursday, March 16, 2017 6:57 AM
To: Buchbinder, Barry (NIH/NIAID) [E] <BBuchbinder@niaid.nih.gov>; Castiblanco, Diana (NIH/NIAID) [C] <diana.castiblanco@nih.gov>; Contreras, Vince (NIH/NIAID) [E] <vince.contreras@nih.gov>; Petrik, Amy (NIH/NIAID) [E] <petrika@niaid.nih.gov>
Subject: FW: ACTION - Fwd: Anyone have objection from KEI in 2017

Please let me know of any objections you are aware of.
Thanks,
Carol

From: Feliccia, Vincent (NIH/NIAID) [E]
Sent: Wednesday, March 15, 2017 6:44 PM
To: Salata, Carol (NIH/NIAID) [E] <CSalata@niaid.nih.gov>; Green, Wade (NIH/NIAID) [E] <wade.green@nih.gov>
Subject: FW: ACTION - Fwd: Anyone have objection from KEI in 2017

RE: Any Objections from KEI in 2017?

Hi Carol and Wade,

Please confirm with your Teams that we have not received any objections from KEI in 2017.

Thanks,

Vince

****

Vincent L. Feliccia, Ph.D., J.D.
Branch Chief
Vaccine Design, Allergic and Infectious Diseases Branch (VDAID)
Technology Transfer and Intellectual Property Office (TTIPO)
National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
5601 Fishers Lane, Suite 6D
MSC 9804
Bethesda, Maryland 20892-9804 [Courier: Rockville, Maryland 20852-9804]

Office: (240) 627-3687
Mobile: (240) 620-2647
Fax: (240) 627-3117
vfeliccia@niaid.nih.gov

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From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Monday, March 13, 2017 8:05 PM
To: Feliccia, Vincent (NIH/NIAID) [E] <VFeliccia@niaid.nih.gov>; Sayyid, Fatima (NIH/NIAID) [E] <fatima.sayyid@nih.gov>; Williams, Richard (NIH/NIAID) [E] <RWILLIAMS@niaid.nih.gov>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <frisbies@otd.nci.nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <MRanjan@niaid.nih.gov>
Subject: ACTION - Fwd: Anyone have objection from KEI in 2017

Branch chiefs,

Please let me know what we've got on this.

To my knowledge none.

Thx,

Mike

Begin forwarded message:

> **From:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Date:** March 13, 2017 at 5:00:29 PM EDT
> **To:** NIH TDC Long <niaaatdcl-l@mail.nih.gov>
> **Subject: Anyone have objection from KEI in 2017**
>
> From FR notice of intent to grant?
>
> Thx
> Mark
>
> Sent from my iPhone

From: Joe Allen [jallen@allen-assoc.com]
Sent: 3/16/2017 7:19:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza

FYI

Sent from my iPhone

See link below for press release that KEI posted this morning. The Inspector General's Office has declined to investigate the federal funding issue for Spinraza.

http://keionline.org/node/2744

From: Robert Hardy [RHardy@COGR.edu]
Sent: 3/17/2017 7:24:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza
Attachments: 18Jan2017-OIG-Investigation-Request-Nusinersen-Patents.pdf

Mark,

Good to see you at AUTM. Hope you got back OK.

Here FYI is the response by the HHS OIG to the KEI request, as well as the original letter from KEI.

Bob

From: Susalka, Stephen [mailto:SSusalka@autm.net]
Sent: Friday, March 17, 2017 11:55 AM
To: Robert Hardy; Joe Allen; Willey, Teri
Cc: Fred Reinhart; Michael Waring; Ashley Stevens (astevens@fipgllc.com)
Subject: RE: HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza

Dear Bob,

I attached the official letter they sent to HHS to this email and their website has the following information:

HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza

- View

- What links here

Submitted by Zack Struver on 16. March 2017 - 8:39
The Department of Health and Human Services Office of Inspector General (OIG) informed KEI that it would not move forward with an investigation into whether Isis Pharmaceuticals, now known as Ionis Pharmaceuticals, failed to report federal funding in patents on Spinraza.

In a letter dated March 13, 2017, Matthew Charette, the Special Agent in Charge of the Investigations Branch of OIG, explained that OIG counsel believes that OIG has limited authority, and that the obligation to "monitor[] invention reporting and remedy[] noncompliance" "rests with NIH's Office of Policy for Extramural Research Administration (OPERA)."

On January 18, 2017, KEI submitted a 22-page letter to OIG containing evidence that the patents on Spinraza benefited from federal grants. KEI did not just ask OIG to investigate Isis' alleged failure to report this funding, in violation of the Bayh-Dole Act and federal regulations, but also urged the OIG "to investigate whether the National Institutes of Health failed to conduct proper oversight in administering its grants" and to "recommend appropriate action to remedy the situation in line with the statute and prior decisions with regard to failure to disclose a subject invention."

Spinraza is used to treat Spinal Muscular Atrophy (SMA), a debilitating illness that largely affects very young children. Biogen, which collaborates with Ionis, sells Spinraza for a price of $750,00 for the first year of four injections, and $375,000 for every year thereafter. As explained in KEI's original letter to OIG, Ionis worked with researchers at Cold Spring Harbor Laboratories who received federal funding for their work on a treatment for SMA. We also noted that failure to disclose federal funding affects the ability of the government to use march-in rights or its royalty-free rights in patents under the Bayh-Dole Act.

The letter from is available as a pdf and transcribed below.

> Mr. Andrew Goldman
> Legal Counsel
> Knowledge Ecology International
> 1622 [sic] Connecticut Avenue, NW, Suite 500
> Washington, DC 20009
>
> Dear Mr. Goldman:
>
> I am responding to your letter dated January 28, 2017, concerning potential violations of the Bayh-Dole Act by Isis Pharmaceuticals, now known as Ionis Pharmaceuticals, and Cold Spring Harbor Laboratory. You requested that the Inspector General investigate whether two inventions patented by Isis and Cold Spring Harbor are Federally-funded subject inventions that should have been disclosed to the National Institutes of Health (NIH) and, if so, recommend an appropriate remedy. We have consulted with our counsel and, as explained below, we believe your requets is better handled by NIH.
>
> Under the Inspector General Act of 1978 (IG Act), OIG may conduct investigations relating to fraud, waste, abuse or other misconduct in connection with programs and operations of HHS. However, OIG's authority is limited. To preserve OIG's independence and objectivity, OIG may not assume responsibility for the operation of a Departmental program. See §§ 4 and 9(a) of the IG Act. Here, the responsibility for administering and overseeing extramural research grants rests with NIH's Office of Policy for Extramural Research Administration (OPERA). This responsibility includes monitoring invention reporting and remedying noncompliance. For this reason, OIG must decline your request.
>
> We did, however, contact representatives from NIH in connection with your letter. We provided NIH with a copy of your letter, and we were informed that NIH/OPERA is currently addressing your concerns. We recommend that you contact NIH/OPERA for further information about this matter.
>
> We hope that this information is useful to you. If you have additional questions, please do not hesitate to contact me or Peter Taschenberger, Senior Counsel at Peter.Taschenberger@oig.hhs.gov or (202) 205-8896.
>
> Sincerely,
> /s/
> Matthew Charette
> Special Agent in Charge
> Investigations Branch
>
> cc: James Love, Director
> Zack Struver, Research Associate
> Diane Singhroy, Scientific Advisor

Sincerely,
Steve

Stephen J. Susalka, Ph.D., CLP
Chief Executive Officer
Association of University Technology Managers (AUTM)
Advancing Discoveries for a Better World
(336) 546-7977
Ssusalka@autm.net

From: Robert Hardy [mailto:RHardy@COGR.edu]
Sent: Friday, March 17, 2017 11:51 AM
To: Joe Allen <jallen@allen-assoc.com>; Willey, Teri <twilley@cshl.edu>
Cc: Fred Reinhart <fred@research.umass.edu>; Michael Waring <mwaring@umich.edu>; Susalka, Stephen <SSusalka@autm.net>; Ashley Stevens (astevens@fipgllc.com) <astevens@fipgllc.com>

Subject: RE: HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza

Can someone please send me the text of the KEI press release?

Thanks. KEI denies me access to their website.

Bob

From: Joe Allen [mailto:jallen@allen-assoc.com]
Sent: Thursday, March 16, 2017 3:26 PM
To: Willey, Teri
Cc: Fred Reinhart; Michael Waring; Susalka, Stephen; Ashley Stevens (astevens@fipgllc.com); Robert Hardy
Subject: Re: HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza

This keeps Jamie's perfect streak (for having every petition denied) intact. He's the Cal Ripken for that category

Sent from my iPhone

On Mar 16, 2017, at 3:15 PM, Willey, Teri <twilley@cshl.edu> wrote:

> And we are continuing to diligently bring all our reporting into compliance. No rest for the wicked.
>
> ---
>
> **From:** Frederick Reinhart [mailto:fred@research.umass.edu]
> **Sent:** Thursday, March 16, 2017 3:14 PM
> **To:** Joe Allen
> **Cc:** Willey, Teri; Michael Waring; Susalka, Stephen; Ashley Stevens (astevens@fipgllc.com)
> **Subject:** Re: HHS Office of Inspector General Declines to Investigate Failure to Disclose Federal Funding in Ionis Pharmaceuticals' Spinraza
>
> Ditto. No doubt they will continue to press the issue.
>
> Sent from my iPhone
>
> On Mar 16, 2017, at 2:54 PM, Joe Allen <jallen@allen-assoc.com> wrote:
>
>> Best news of the day!
>>
>> Sent from my iPhone
>>
>> On Mar 16, 2017, at 2:02 PM, Willey, Teri <twilley@cshl.edu> wrote:
>>
>>> Sharing some positive news
>>>
>>> See link below for press release that KEI posted this morning. The Inspector General's Office has declined to investigate the federal funding issue for Spinraza.
>>>
>>> http://keionline.org/node/2744

KNOWLEDGE ECOLOGY INTERNATIONAL

1622 Connecticut Ave NW Suite 500
Washington, D.C. 20009
+1 (202) 332-2670
http://keionline.org

January 18, 2017

The Honorable Daniel R. Levinson
U.S. Department of Health & Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201
via email: Dan.Levinson@oig.hhs.gov

Dear Inspector General Levinson:

RE: Allegation of Isis Pharmaceuticals Failure to Satisfy Disclosure Requirements for a Subject Invention Under the Bayh-Dole Act, 35 U.S.C. §§ 200 *et seq.*

This letter requests that you investigate substantial evidence that Isis Pharmaceuticals (now known as Ionis Pharmaceuticals) and Cold Spring Harbor Laboratory failed to satisfy disclosure requirements under the Bayh-Dole Act, 35 U.S.C. §§ 200 *et seq.*, and Federal regulations, 37 C.F.R. §§ 401.3(a) & 401.14, with regard to federally-funded subject inventions related to the composition and methods of use of nusinersen, an antisense oligonucleotide (ASO), for the treatment of spinal muscular atrophy (SMA), embodied in U.S. Patent Nos. 8,361,977 (hereinafter the "'977 patent") and 8,980,853 (hereinafter the "'853 patent").

We have a high degree of confidence that both the '977 patent and the '853 patent are subject inventions under the Bayh-Dole Act, in that they were "conceived or first actually reduced to practice in the performance of work under a funding agreement." 35 U.S.C. § 201(e).

Specifically, we present evidence that both inventions benefitted from the grant of funds from the National Institutes of Health (NIH) to support the research of Dr. Adrian R. Krainer at Cold Spring Harbor Laboratory, which was then used to file patents that have been assigned to Isis.

In addition, the National Institutes of Health (NIH) gave several grants to Isis, and those grants appear to have directly contributed to the reduction to practice of the patented inventions assigned to Isis.

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I. About Us

Knowledge Ecology International (KEI) is a 501(c)(3) non-profit non-governmental organization based in Washington, D.C., that advocates for access to affordable medicines, with a focus on human rights and social justice.

KEI has conducted oversight of federal intellectual property policy as it relates to federally-funded inventions. Over the years, we have filed petitions and comments with various federal agencies, including the National Institutes of Health, in regards to the grant of intellectual property licenses and the use of federal authorities to end monopolies under the

Bayh-Dole Act. See, for example, our recent work on the exclusive licensing of federally owned inventions by the National Institutes of Health, http://keionline.org/nih-licenses . See also our petition to the National Institutes of Health and the U.S. Army to use march-in rights (35 U.S.C. § 203) or the government's royalty-free license in the patents (35 U.S.C. § 202(c)(4)) on the prostate cancer drug Xtandi as a mechanism to lower the excessive price of the drug in the United States, http://keionline.org/xtandi .

II. Spinal Muscular Atrophy (SMA) and Nusinersen (Spinraza)

II.A. Spinal Muscular Atrophy Incidence, Presentation, and Genetics

Spinal Muscular Atrophy (SMA) is a genetic neuromuscular disease that affects the nervous system, in particular control of muscle movement.[1] The disease results in muscle weakness and wasting, difficulty breathing, and paralysis.

SMA is the primary genetic cause of infant death.[2]

Current estimates for incidence range from 1 in 6,000 to 1 in 10,000 live births. Approximately 1 in 40 to 1 in 60 people carry the gene that contributes to the disorder. Because SMA is recessive, both parents must carry the gene in order for the disease to present.

Clinicians classify SMA "into four phenotypes on the basis of age of onset and motor function achieved."[3]

The following table from D'Amico et al. shows the classifications:

Table II.1: Classifications of Spinal Muscular Atrophy (SMA)

	Age of Onset	**Highest function achieved**
Type I (Werdnig-Hoffmann disease)	0-6 months	Never sit
Type II (intermediate)	7-18 months	Sit never stand
Type III (mild, Kugelberg-Welander disease) in adulthood	> 18 months	Stand and Walk during adulthood
Type IV (adult)	2°-3° decade	Walk unaided

---

[1] This section draws upon Adele D'AMico et al., *Spinal Muscular Atrophy*, 6 Orphanet J. Rare Diseases 71 (2011), unless otherwise stated.
[2] Cure SMA, About SMA, http://www.curesma.org/sma/about-sma/.
[3] D'Amico, *Spinal Muscular Atrophy*.

The most common form of SMA is Type I, causing severe symptoms and death, as D'Amico *et al.* write:

> SMA type 1 (Werdnig-Hoffmann disease) is the most severe and common type, which accounts for about 50% of patients diagnosed with SMA. Classically infants with SMA type I have onset of clinical signs before 6 months of age, never acquire the ability to sit unsupported and, if no intervention is provided, generally do not survive beyond the first 2 years. These patients have profound hypotonia, symmetrical flaccid paralysis, and often no head control. Spontaneous motility is generally poor and antigravity movements of limbs are not typically observed. In the most severe forms decreased intrauterine movements suggest prenatal onset of the disease and present with severe weakness and joint contractures at birth and has been labeled SMN 0. Some of these children may show also congenital bone fractures and extremely thin ribs. (Citations excluded.)

Everyone has two SMN genes, SMN1 and SMN2, to produce the SMN protein. In individuals with SMA, the SMN1 gene is defective and cannot be used to produce SMN protein. They must therefore rely solely on SMN2 gene to make the SMN protein. However, the SMN2 gene is not as efficient at making full length SMN protein and does not produce enough of the functional protein to make up for the loss of SMN1. This affects several cellular processes in motor neurons resulting in their degeneration, causing the muscles under their control begin to atrophy.[4]

II.B. Nusinersen (Spinraza) Mechanism of Action and Efficacy

Nusinersen, marketed by Biogen under license from Ionis Pharmaceuticals as Spinraza, is the first treatment for pediatric and adult SMA approved for sale in the United States by the Food and Drug Administration.[5]

The FDA approved nusinersen as a New Drug Application under Priority Review. In addition, the FDA granted nusinersen Orphan Designation, which enabled Biogen to claim the 50-percent orphan drug tax credit on qualifying clinical trials, and affords Biogen seven years of marketing exclusivity from the date of approval of the NDA.[6]

---

[4] Saif Ahmad et al., *Molecular Mechanisms of Neurodegeneration in Spinal Muscular Atrophy*, 10 J. Experimental Neurosci. 39 (2016).

[5] Biogen, *U.S. FDA Approves Biogen's SPINRAZA™ (nusinersen), The First Treatment for Spinal Muscular Atrophy*, Dec. 23, 2016, http://media.biogen.com/press-release/neurodegenerative-diseases/us-fda-approves-biogens-spinraza-nusinersen-first-treatment

[6] Nusinersen received orphan designation on April 18, 2011. See the FDA database of Orphan Drug Designations and Approvals, at https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=33671.Both of the

The high price of nusinersen — $750,000 for the first year of treatment and $375,000 for every year thereafter — generated significant controversy, as reported in *FiercePharma*: "Regardless of how fair or reasonable Spinraza's sticker might be in the ultra-orphan context, however, the outsize price tag was guaranteed to raise eyebrows, given the close scrutiny drug prices currently face."[7]

As mentioned in the previous section, patients with SMA have a defective SMN1 gene, which leaves their body with an insufficient amount of the SMN protein and causes the death of motor neurons and muscular degeneration. Nusinersen acts on SMN2 unspliced mRNA transcripts and helps it make full length functional SMN protein, thus compensating for the malfunctioning SMN1 gene.

FDA approval of nusinersen was based on the interim results of a phase 3 double blind randomized clinical trial, ENDEAR (NCT02865109), and phase 3 open-label clinical trial, SHINE (NCT02594124).

ENDEAR enrolled 121 infants less than 7 months of age, and 82 were eligible for analysis at the time. According to the FDA label, the primary endpoint measured was "improvement in motor milestones according to Section 2 of the Hammersmith Infant Neurologic Exam (HINE)." The analysis demonstrated "statistically significant improvements in motor milestones, and the drug was generally well-tolerated, with a favorable safety profile and no significant adverse events."[8]

The SHINE study, conducted in patients 30 days to 15 years, supported the ENDEAR results, such that, according to the FDA label, "some patients achieved milestones such as ability to sit unassisted, stand, or walk when they would otherwise be unexpected to do so, maintained milestones at ages when they would be expected to be lost, and survived to ages unexpected considering the number of SMN2 gene copies of patients enrolled in the studies."

---

phase III studies cited in the FDA label for nusinersen were conducted after the FDA granted orphan designation, making them eligable for the orphan drug tax credit.

[7] Tracy Staton, *Biogen's $375K Spinraza Price Puts a Sovaldi-Style Spotlight on Rare Disease Meds*, FiercePharma, Jan. 3, 2017, http://www.fiercepharma.com/pharma/biogens-375k-spinraza-price-puts-a-sovaldi-style-spotlight-rare-disease-meds.

[8] Carolina Henriques, *Regulatory Applications for SMA Therapy Nusinersen Accepted in US and EU*, SMA News Today, Nov. 1, 2016, https://smanewstodaycom/2016/11/01/regulatory-applications-sma-therapy-nusinersen-accepted-us-fda-eu-ema.

III. The Bayh-Dole Act and Disclosure of Subject Inventions

The Bayh-Dole Act and Federal regulations and guidelines make clear several obligations for contractors in the disclosure of government rights in subject inventions, including: (1) a requirement to disclose that federal funding contributed to an invention; (2) NIH contractual requirements for disclosure; and (3) required language to be inserted in patent applications and the patents, stating the role of federal funding and the government's rights.

First, contractors are required to disclose subject inventions discovered with federal funding in a timely manner and with sufficient detail to describe the invention.

Under 35 U.S.C. § 202(c)(1), any contractor that receives funding from the federal government is required to "disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters."[9]

Under 37 C.F.R. § 401.3(a), each federal funding agreement shall contain the "standard patent rights clause" found at 37 C.F.R. § 401.14(a), barring specific circumstances and exceptions.[10] Subsection (c)(1) of the patent rights clause outlines the disclosure requirements, including a two month time limit on the disclosure of patents and a requirement that the disclosure have sufficient detail:[11]

37 C.F.R. § 401.14(a)(c)(1)

(c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the *agency* shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*,

---

[9] The statute defines a "subject invention" at 35 U.S.C. § 201(e) as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement," and defines a contractor at 35 U.S.C. § 201(c) as "any person, small business firm, or nonprofit organization that is party to a funding agreement."

[10] The exceptions do not contain reference to the disclosure requirements.

[11] Italics in original.

> the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor*.
>
> . . .
>
> (4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency*, be granted.

Second, in implementing this regulation, the National Institutes of Health requires contractors to disclose subject inventions via iEdison, an online electronic system for reporting inventions and patents discovered under federal grants, and via HHS Form 568, entitled, "Final Invention Statement and Certification (For Grant or Award)," available at: https://grants.nih.gov/grants/hhs568.pdf .

The NIH specifies the required information on an FAQ related to the use of iEdison, and also notes that contractors should disclose the subject invention even if they have, in the past, failed to report the invention within the two month period:[12]

> **5. What information is required to report a subject invention?**
>
> The invention disclosure must include the following information:
>
> -Either the EIR Number, Invention Docket Number, or both.
>
> -Invention Title
>
> -Names of all of the inventors and the institutions with which they are associated
>
> -Invention Report Date
>
> -Description of the Invention that must meet the standards set forth per 37 CFR Sec. 401.14 (a)(c)(1):
>
> > **". . . be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention."37 C.F.R. 401.14(a)(c)(1)"**
>
> -Primary Funding Agency
>
> -All funding agreement numbers and names of the funding agencies

---

[12] Available at: https://era.nih.gov/iedison/iedison_faqs.cfm#VIII5(accessed Jan. 6, 2017).

> - Any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure
>
> **9. If I upload a patent application, can that patent application satisfy the Invention Disclosure Report requirement?**
>
> Yes, so long as the EIR Number or Invention Docket Number is included on the submission, the patent record containing the patent/patent application number has been reported in iEdison, and you upload proof that the patent application was filed with the USPTO, e.g., a USPTO submission receipt.
>
> **10. What should a grantee/contractor do if a subject invention hasn't been reported to the awarding agency within the required 2 month period?**
> Always report the invention, even if it is late. The invention report date should be the date the inventor notified the awardee institution of the subject invention. Provide an explanation in the "Explanatory Notes" section of the invention record.

On February 17, 2016, NIH issued a notice entitled "Reminder: All Subject Inventions Must Be Reported on the HHS 568 - Final Invention Statement and Certification (For Grant or Award) and in iEdison." The notice explained that failure to disclose the subject invention via both iEdison and Form 568 could result in the loss of rights in the invention.[13] As explained below in section V on remedies, this notice is consistent with precedent related to failure to disclose.

Finally, under 35 U.S.C. § 202(c)(6) and 37 C.F.R. § 1.77(b)(3), contractors are required to state within the patent application that the federal government contributed funding to support the discovery of the invention and that the government retains certain rights:

> **35 U.S.C. § 202(c)(6)**
> (c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:
>
> …
>
> (6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

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[13] National Institutes of Health, Reminder: All Subject Inventions Must Be Reported on the HHS 568 - Final Invention Statement and Certification (For Grant or Award) and in iEdison, NOT-OD-16-066 (Feb. 17, 2016), NIH Guide Notice, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-066.html.

35 C.F.R. § 1.77(b)(3)

(b) The specification should include the following sections in order:

. . .

(3) Statement regarding federally sponsored research or development.

The Manual of Patent Examining Procedure contains the following recommended language:

> "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention." [14]

IV. The Nusinersen Patent Landscape and Failure to Disclose Government Rights in a Subject Invention

This section will outline the patent landscape for nusinersen and explain the failure of Isis Pharmaceuticals to disclose federal funding in the work that contributed to the '977 and '853 patents, in violation of 35 U.S.C. § 202(c)(1).

Ionis claimed five United States patents as the "key … patents protecting nusinersen" in its 2015 Securities and Exchange Commission 10-K filing.[15]

Table IV.1: Key United States Patents in Nusinersen

Patent No.	Title	Priority Date	Filing Date	Expiration Date	Original Assignee
6,210,892	ALTERATION OF CELLULAR BEHAVIOR BY MODULATION OF MRNA PROCESSING	Oct. 7, 1998	Mar. 26, 1999	2018	Isis Pharmaceuticals, Inc.

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[14] MPEP (9th ed. Rev. 07.2015, Nov. 2015), § 310.

[15] Ionis Pharm., Inc., Annual Report (Form 10-K), (Feb. 25, 2016). The Food and Drug Administration (FDA) approved nusinersen for the treatment of spinal muscular atrophy based upon New Drug Application No. 209531 on December 23, 2016. Drugs@FDA Database. Due to the recent approval date, the patents for nusinersen are not yet listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the Orange Book.

7,838,657	SPINAL MUSCULAR ATROPHY (SMA) TREATMENT VIA TARGETING OF SMN2 SPLICE SITE INHIBITORY SEQUENCES	Dec. 3, 2004	Dec. 5, 2005	2027	University of Massachusetts
8,110,560	SPINAL MUSCULAR ATROPHY (SMA) TREATMENT VIA TARGETING OF SMN2 SPLICE SITE INHIBITORY SEQUENCES	Dec. 3, 2004	Aug. 21, 2009	2025	University of Massachusetts
8,361,977	COMPOSITIONS AND METHODS FOR MODULATION OF SMN2 SPLICING	June 23, 2005	June 23, 2006	2030	Isis Pharmaceuticals, Inc.
8,980,853	COMPOSITIONS AND METHODS FOR MODULATION OF SMN2 SPLICING IN A SUBJECT	June 17, 2009	June 17, 2010	2030	Isis Pharmaceuticals, Inc.; Cold Spring Harbor Laboratory

We will not address the ’892 patent, which is set to expire next year, nor will we address a European patent that is identical to the ’977 patent (European Patent No. 1910395).

IV.A. The University of Massachusetts Patents

The patents owned by the University of Massachusetts describe the composition (U.S. Patent No. 7,838,657) and the method of use (8,110,560) of “oligonucleotide reagents (e.g., oligoribonucleotides) that effectively target the SMN2 ISS-N1 site in the SMN2 pre-mRNA, thereby modulating the splicing of SMN2 pre-mRNA to include exon 7 in the processed transcript.”

The laboratory of Dr. Ravindra N. Singh invented the ’657 and ’560 patents in the course of research on the “molecular basis of Spinal Muscular Atrophy.”[16]

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[16] Iowa State University, Ravindra N. Singh, Research Focus & Interests, https://vetmed.iastate.edu/users/singhr

The patents list Dr. Ravindra N. Singh, Dr. Natalia N. Singh, Dr. Nirmal K. Singh, and Dr. Elliot J. Androphy as inventors.

Both patents acknowledge federal funding from the National Institutes of Health in support of the work described in the patent, and also acknowledge the government's retained rights:

> Funding for the work described herein was at least in part provided by the federal government (N.I.H. grant R01 NS40275). The government may, therefore, have certain rights in the invention.

The NIH awarded grant R01 NS40275 to Dr. Elliot J. Androphy, who at the time of the discovery of the invention directed the joint M.D./Ph.D. program at the University of Massachusetts Medical School.[17]

The University of Massachusetts licensed the patents to Isis Pharmaceuticals on January 14, 2010.[18]

KEI has requested additional information on the research and resulting intellectual property from the University of Massachusetts through a request under the Massachusetts Public Records Law, Mass. Gen. Laws ch. 66, §10 (2017).

IV.B. The '977 and '853 Patents: Failure to Disclose Government Rights in the Patents

The '977 and '853 Patents are, respectively, a compound patent and method of use patent for nusinersen as a treatment for SMA. We believe that Isis Pharmaceuticals and Cold Spring Harbor Laboratory failed to disclose that the inventions in the patents are subject inventions under the Bayh-Dole Act, as required by 35 U.S.C. § 202(c)(1).

The '977 patent is assigned to Isis Pharmaceuticals, and was invented by employees of Isis and Cold Spring Harbor Laboratory, a nonprofit research laboratory located on Long Island in New York. The inventor Brenda F. Baker was at the time of the patent application filing date employed by Isis, while Adrian R. Krainer was a Professor at Cold Spring Harbor Laboratory, and Yimin Hua was a Postdoctoral Fellow and later a Research Investigator at Cold Spring Harbor Laboratory. Before joining Cold Spring Harbor Laboratory in July 2004, Yimin Hua was a postdoctoral fellow at Tufts and the University of Massachusetts, studying SMA/SMN.[19]

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[17] See the NIH RePORTER database for additional information on the UMass grants: https://projectreporternih.gov/Reporter_Vewsh.cfm?sl=12EBCD0F4888C4D37598B8961CAA4A01A2FFCEB861BF.

[18] UMass Agreement No: UMMS 05-19-03, https://www.sec.gov/Archives/edgar/data/874015/000087401514000095/ex10_1.htm

[19] https://www.linkedin.com/in/yimin-hua-6b583956

The ’853 patent is assigned to both Isis and Cold Spring, and lists amongst its inventors employees of Isis, Genzyme, and Cold Spring Harbor:[20]

- C. Frank Bennett — Isis Senior Vice President for Research
- Gene Hung — Isis
- Frank Rigo — Isis
- Adrian R. Krainer — Professor, Cold Spring Harbor Lab
- Yimin Hua — Postdoctoral Fellow and Research Investigator, Cold Spring Harbor Lab
- Marco A. Passini — Researcher, Genzyme
- Lamya Shihabuddin — Senior Director, Genzyme
- Seng H. Cheng — Group Vice President, Genetic Diseases Science, Genzyme
- Katherine W. Klinger — Senior Vice President, Genetics and Genomics, Genzyme

A news story published in October 2016 in Nature Biotechnology describes how the collaboration between Isis and Dr. Krainer of Cold Spring Harbor came about:

> “The one-nucleotide change that causes SMN2 to skip an exon prevents a splicing activator from binding. Krainer began experimenting with a peptide designed to trigger the splicing of SMN2 exon 7 and its inclusion in the SMN2 pre-mRNA, thus creating a full-length, stable SMN2 protein. **He linked an antisense molecule to the peptide just to direct it to the correct region on SMN2, but to Krainer’s surprise the antisense alone was able to correct the splicing defect, although not as potently. “An important and lucky observation,” says Krainer. “We didn’t expect it, and we didn’t initially understand it.” Upon publication of the finding, Ionis contacted Krainer and began collaborating with him** (Nat. Struct. Biol. 10, 120–125, 2003).
>
> “Ionis brought its antisense technology to the table. The company’s 2′-O-methoxyethyl (2′MOE) phosphorothioate chemistry, with sulfur substituting for one of the non-bridging oxygen atoms in the phosphate backbone, and chemical modification of the sugar at the 2′ position, helps resist nuclease degradation and enhances cell penetration. It thus was an excellent in vivo splicing modifier. **Krainer and Isis screened over 500 different antisense molecules against various sites on SMN2 exon 7 and its adjacent introns. The best at splicing exon 7 into the SMN2 pre-mRNA was nusinersen, an 18-nucleotide antisense oligo that blocks the intronic binding site of a splicing repressor.** Because nusinersen binds a unique sequence, it shouldn’t have off-target effects, says Krainer, and because the target is on an intron that’s spliced out of the protein, the drug comes off and doesn’t interfere with SMN2 translation. Blocking this single site is enough for the drug to achieve up to

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[20] All employments listed below indicate employment at the time that the patent application for the ’853 patent was filed.

> 90% exon 7 inclusion in SMN2 transgenic mice (Am. J. Hum. Gen. 82, 834–848, 2008). Human trials began in 2011."[21]

Dr. Krainer published his initial findings (the first finding described above in the Nature Biotechnology story, that we should target SMN2 to treat SMA) in 2003 in Nature Structural Biology with Dr. Luca Cartegni, then a Post-Doc at Cold Spring Harbor:

- Luca Cartegni and Adrian R. Krainer, *Correction of Disease-Associated Exon Skipping by Synthetic Exon-Specific Activators*, 10 Nature Structural Biology 120-125 (2003).

In the acknowledgements section, Dr. Cartegni and Dr. Krainer acknowledged support from the National Institutes of Health, without providing a particular grant number. Cartegni and Krainer, 125.

In 2008, Dr. Krainer and members of his lab co-authored a paper with C. Frank Bennett and Timothy A. Vickers of Isis Pharmaceuticals identifying the sequence for nusinersen:

- Yimin Hua, Timothy A. Vickers, Hazeem L. Okunola, C. Frank Bennett & Adrian R. Krainer, *Antisense Masking of an hnRNP A1/A2 Intronic Splicing Silence Corrects* SMN2 *Splicing in Transgenic Mice*, 82 Am. J. Human Genetics 834-848 (2008).

The acknowledgements in this paper also cited NIH funding, this time providing a particular grant number:

> "We thank Chaolin Zhang for help with hnRNP A1 PWM analysis and Xavier Roca and Michelle Hastings for useful comments on the manuscript. We also thank A. Burghes for helpful discussions. Y.H. and A.R.K. gratefully acknowledge support for this work from the SMA Foundation, the Muscular Dystrophy Association, the Louis Morin Charitable Trust, and **National Institutes of Health grant GM42699**. T.A.V. and C.F.B. are employees of Isis Pharmaceutical, the owner of the antisense oligonucleotide chemistry used in this report, and materially benefit either directly or indirectly through stock options. Y.H. and A.R.K., along with their employer, Cold Spring Harbor Laboratory, could materially benefit if a therapeutic for SMA results from this work. A.R.K. serves on the scientific advisory board of two nonprofit SMA foundations."[22]

The NIH RePORTER database shows that Dr. Krainer has received funding from the NIH under grant number GM42699 since at least 1993 (the earliest date in the database). Between 2006 and 2007 (the year in which the paper was submitted to the journal), Dr. Krainer received $1,175,935 in funding under the grant. Over the course of the past 23 years,

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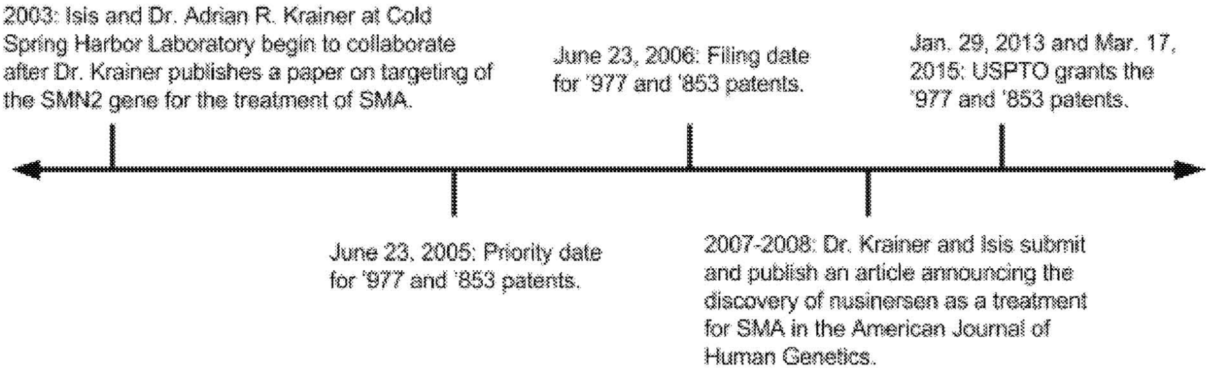
[21] Ken Garber, *Big Win Possible for Ionis/Biogen Antisense Drug in Muscular Atrophy*, 34 Nature Biotech. 1002, 100 (2016) (emphasis added).
[22] Hua et al., 846 (emphasis added).

Dr. Krainer has received $11,701,483 in funding under this grant. See Appendix I for additional information on Dr. Krainer's grants.

We have a high degree of confidence that the Krainer grants contributed directly to the reduction of practice of nusinersen as a treatment for SMA because of the federal funding acknowledged in the paper and the overlap between the findings described in the paper and the patent.

Figure IV.1: Timeline of Publications, Collaborations, and Patent Filings/Grants


2003: Isis and Dr. Adrian R. Krainer at Cold Spring Harbor Laboratory begin to collaborate after Dr. Krainer publishes a paper on targeting of the SMN2 gene for the treatment of SMA.
June 23, 2006: Filing date for '977 and '853 patents.
Jan. 29, 2013 and Mar. 17, 2015: USPTO grants the '977 and '853 patents.
June 23, 2005: Priority date for '977 and '853 patents.
2007-2008: Dr. Krainer and Isis submit and publish an article announcing the discovery of nusinersen as a treatment for SMA in the American Journal of Human Genetics.

The above timeline of events shows that Isis and Dr. Krainer started their collaboration shortly after Dr. Krainer published his 2003 paper, which benefitted from public funding. The research that led to the discovery of nusinersen as a treatment for SMA, then, was conducted between 2003 and 2005 — the priority date listed on both the '977 and '853 patents. Shortly after the patent filing date of June 23, 2006, Isis and Dr. Krainer likely began work on drafting their paper, which was submitted in 2007 and accepted for publication in 2008. The paper, as stated previously, acknowledged that NIH funding contributed to the research to discover that nusinersen could be used as a treatment for SMA.

Dr. Krainer and colleagues identified the antisense oligonucleotide (ASO) that would best correct SMN2 splicing in their 2008 *American Journal of Human Genetics* publication:

> "After elucidating the exact position and mechanism of the intron 7 ISS, we optimized the most potent ASOs that target this silencer and used them to try to rescue SMN2 splicing in mice harboring a human SMN2 transgene. First, we synthesized 38 ASOs of different lengths and examined their effects on splicing of transcripts of the endogenous SMN2 gene in HEK293 cells."[23]

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[23] Yimin Hua, Timothy A. Vickers, Hazeem L. Okunola, C. Frank Bennett & Adrian R. Krainer, *Antisense Masking of an hnRNP A1/A2 Intronic Splicing Silence Corrects* SMN2 *Splicing in Transgenic Mice*, 82 Am. J. Human Genetics 834, 842-3 (2008).

They found that ASO 10-27 and 09-23 were the best candidates for further testing in transgenic mice. Ultimately, the ASO 10-27 sequence was chosen for nusinersen.

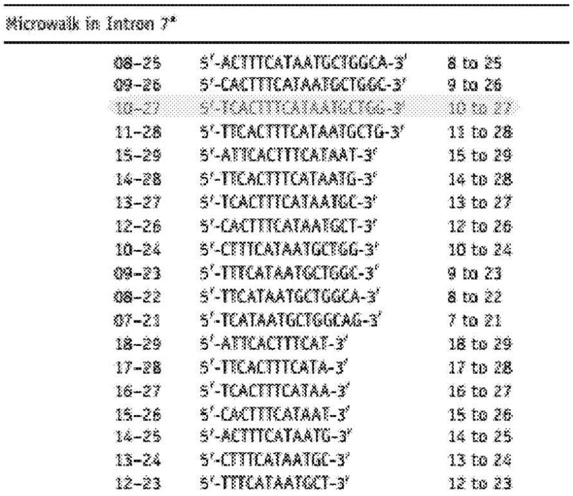
ASO 10-27 is the same as the gene sequence for nusinersen as listed in the ’977 and ’853 patents.

The ’853 patent claims the following:

> 1. A method comprising administering by a bolus injection into the intrathecal space of a subject with infantile-onset type I spinal muscular atrophy (SMA) an antisense compound comprising an antisense oligonucleotide consisting of 18 linked nucleosides, wherein the oligonucleotide has a nucleobase sequence consisting of the nucleobase sequence SEQ ID NO: 1, wherein each internucleoside linkage of the oligonucleotide is a phosphorothioate linkage, wherein each nucleoside of the oligonucleotide is a 2′-MOE nucleoside, and wherein the administering of the antisense compound ameliorates at least one symptom of SMA in the subject.
>
>> 2. The method of claim 1, wherein the antisense compound is administered at a dose from 0.5 to 10 milligrams of antisense compound per kilogram of body weight of the subject.
>>
>> 3. The method of claim 1, wherein inclusion of exon 7 of SMN2 mRNA in a motoneuron in the subject is increased.
>>
>> 4. The method of claim 1, wherein a 5 mg to 20 mg dose of antisense is administered.

SEQ ID NO: 1, as described in claim 1, is the following: TCACTTTCATAATGCTGG.

The 2008 collaborative paper published by Cold Spring Harbor and Isis, which benefitted from federal funding, also identifies sequence number 1 in Table 1, as ASO 10-27:



Microwalk in Intron 7*		
08-25	5′-ACTTTCATAATGCTGGCA-3′	8 to 25
09-26	5′-CACTTTCATAATGCTGGC-3′	9 to 26
10-27	5′-TCACTTTCATAATGCTGG-3′	10 to 27
11-28	5′-TTCACTTTCATAATGCTG-3′	11 to 28
15-29	5′-ATTCACTTTCATAAT-3′	15 to 29
14-28	5′-TTCACTTTCATAATG-3′	14 to 28
13-27	5′-TCACTTTCATAATGC-3′	13 to 27
12-26	5′-CACTTTCATAATGCT-3′	12 to 26
10-24	5′-CTTTCATAATGCTGG-3′	10 to 24
09-23	5′-TTTCATAATGCTGGC-3′	9 to 23
08-22	5′-TTCATAATGCTGGCA-3′	8 to 22
07-21	5′-TCATAATGCTGGCAG-3′	7 to 21
18-29	5′-ATTCACTTTCAT-3′	18 to 29
17-28	5′-TTCACTTTCATA-3′	17 to 28
16-27	5′-TCACTTTCATAA-3′	16 to 27
15-26	5′-CACTTTCATAAT-3′	15 to 26
14-25	5′-ACTTTCATAATG-3′	14 to 25
13-24	5′-CTTTCATAATGC-3′	13 to 24
12-23	5′-TTTCATAATGCT-3′	12 to 23

The ’853 patent makes the link explicit by citing the 2008 paper.

The ’977 patent also relied on the research from the Cold Spring Harbor/Isis collaboration, similarly identifying the sequence in the first claim of the ’853 patent.

IV.B.1 Federal grants to ISIS Pharmaceuticals

Isis has also received federal funding for its work on antisense-based drugs, which may have contributed to the research on the development of nusinersen.[24] For example, project number 1R43GM058974-01 describes the development of antisense oligonucleotides, with the following proposed commercial applications:

> “Therapeutic antisense oligonucleotides are potentially a multibillion-dollar industry. Commercialization of antisense oligonucleotides against viral, cellular and cancer targets is limited by the pharmacokinetic and pharmcodynamic properties of existing first generation 2'-deoxy phosphorothioate drugs. RNA modifications which enhance target affinity and biostability can lead to antisense drugs of (i) shorter length (which translates to improved absorption and lower production cost), and (ii) less frequent dosing, and (iii) higher target specificity, and hence less toxicity.”[25]

Overall, the NIH has provided Isis with at least $17,509,977 in total funding since 1993. Between 2003 and 2006, the period that nusinersen was in development, Isis received $10,821,633 in grants from DHHS, not including grants received from the US Army and

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[24] See Appendix I for additional information on the Isis grants.

[25] https://projectreporter.nih.gov/project_info_description.cfm?aid=2792656&icde=32525907&ddparam=&ddvalue=&ddsub=&cr=25&csb=default&cs=ASC&pball=

DARPA. In general, however, the NIH funding to Cold Spring Harbor Laboratory is the most direct and compelling evidence regarding the federal funding of the inventions.

V. Remedies

In addition to investigating the above evidence related to the possibility that Isis failed to disclose subject inventions, the Office of the Inspector General should explore relevant remedies to rectify the alleged failure to disclose the subject inventions in the '977 and '853 patents.

In particular, failure to disclose subject inventions pursuant to 35 U.S.C. § 202(c)(1) permits the Federal Government to "**receive title to any subject invention not disclosed to it within such time**" (emphasis added).

In the past, the Federal Government has utilized its authority to claim title in subject inventions that have not been properly disclosed, as in the case of *Campbell Plastics Engineering & Mfg., Inc. v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004) (finding that federal government claim of title in invention was legitimate under federal acquisition regulations and supported by the Bayh Dole Act where disclosure submissions were "piecemeal" and violated the contractual agreement with the government); *see also Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352-53 (Fed. Cir. 2007) ("Critically, *Campbell Plastics* holds that a Bayh–Dole violation grants the government *discretionary* authority to take title. . . . When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable.").

In *Campbell Plastics*, the court found that the contract was clear and unambiguous, but moreover the government's claim to title was "buttressed by the policy considerations behind the Bayh Dole Act." *Id.* at 1248. These include, specifically under 35 U.S.C. § 200, the need "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."

VI. Concluding Comments

On behalf of patients, taxpayers, employers and everyone who pays for health care, we ask your office to investigate whether Isis and/or Cold Spring Harbor failed to comply with the provisions of the Bayh-Dole Act requiring the disclosure of federal funding in patents related to nusinersen.

We also ask your office to investigate whether the National Institutes of Health failed to conduct proper oversight in administering its grants.

Finally, we ask you to recommend appropriate action to remedy the situation in line with the statute and prior decisions with regard to failure to disclose a subject invention.

The failure to disclose federal funding in nusinersen is significant because it affects the disposition of the federal government's rights to end the patent monopoly and authorize generic manufacture under the march-in provisions and government royalty-free right in the Bayh-Dole Act.

KEI and other public interest groups have asked the government to use those rights to lower the excessive price of pharmaceuticals in the past. (See http://keionline.org/xtandi). We intend to ask the NIH to initiate a march-in case for the federally-funded patents on nusinersen over the excessive price ($750,000 in the first year and $375,000 per year thereafter for maintenance doses), and also to ask Medicare or other federal agencies to use their royalty free rights in the drug to authorize the manufacture and sale of generic versions of the drug at reasonable prices. We believe the Trump administration will take a different view than the Obama Administration on the issue of charging excessive prices on federally funded medical inventions.

We recognize that nusinersen benefits from non-patent exclusivities, including Orphan Drug exclusivity and exclusive rights in test data. However, Congress is likely to consider exceptions to such exclusivity in the coming years, and in any event, the patent term exceeds any non-patent exclusivities. Resolving access to the federally-funded inventions via march-in or the royalty free right provides the federal government with much greater leverage to lower the price of this treatment for a very severe disease.

We would like to meet with you and your staff to discuss how we can assist you in moving forward with an investigation.

Sincerely Yours,

James Love, Director
Knowledge Ecology International

Andrew Goldman, Legal Counsel
Knowledge Ecology International

Zack Struver, Research Associate
Knowledge Ecology International

Diane Singhroy, Scientific Advisor
Knowledge Ecology International

CC: Gary Cantrell, Deputy Inspector General for Investigations, Gary.Cantrell@oig.hhs.gov

Appendix I: Information on Misc Grants

1. Adrian R. Krainer / Cold Spring Harbor Laboratory Grant No. GM42699

For additional information, see the following query results from the NIH RePORTER database: https://projectreporter.nih.gov/Reporter_Viewsh.cfm?sl=12EBCD034889C4DF7598B8961CAA4A01A2FFCEB861BF

Dr. Krainer's grants for the project entitled "Biochemistry of Pre-mRNA Splicing" are administered by the National Institute of General Medical Sciences (NIGMS).

Fiscal Year (FY)	FY Total Cost
2016	$746,014
2015	$746,014
2014	$734,358
2013	$708,654
2012	$728,529
2010	$656,937
2009	$638,359
2008	$643,281
2007	$620,984
2006	$554,951
2005	$551,995
2004	$535,378
2003	$517,746
2001	$451,541
2000	$438,566
1999	$425,968
1998	$418,728
1997	$349,086
1996	$335,762
1995	$323,426
1994	$312,002
1993	$263,204

2. *Isis Pharmaceuticals' Grants from RePORTER query*

For additional information, see the following query results from the NIH RePORTER database: https://projectreporter.nih.gov/Reporter_V iewsh.cfm?sl=12EBCC094B84C6D0 7598B8961CA A4A01A2FFCEB861BF

Isis Pharmaceuticals' grants are administered by various components of the National Institutes of Health, or the CDC, under several different grant numbers.

Project Title	IC	Project Number	Contact PI / Project Leader	FY	FY Total Cost
ANTISENSE INHIBITORS OF HERPES SIMPLEX VIRUS REPLICATION	NIAID	2R44AI030331-02	ANDERSON, KEVIN P	1993	$193,250
OLIGONUCLEOTIDES AS INHIBITORS OF PAPILLOMAVIRUSES	NCI	2R44CA052391-02	COWSERT, LEX	1993	$118,544
ANTISENSE INHIBITORS OF HERPES SIMPLEX VIRUS REPLICATION	NIAID	5R44AI030331-03	ANDERSON, KEVIN P	1994	$223,920
5' CAP--A NOVEL TARGET FOR ANTISENSE TECHNOLOGY	NIAID	2R44AI030333-02A1	BAKER, BRENDA F	1994	$242,708
SEQUENCE SPECIFIC SYNTHETIC MRNA CLEAVING AGENTS	NIGMS	1R41GM051646-01	BAKER, BRENDA F	1994	$100,000
OLIGONUCLEOTIDES AS INHIBITORS OF PAPILLOMAVIRUSES	NCI	5R44CA052391-03	COWSERT, LEX M	1994	$246,302
5' CAP--A NOVEL TARGET FOR ANTISENSE TECHNOLOGY	NIAID	5R44AI030333-03	BAKER, BRENDA F	1995	$253,349
OLIGONUCLEOTIDES AS INHIBITORS OF PAPILLOMAVIRUSES	NCI	5R44CA052391-04	COWSERT, LEX M	1995	$127,758
ANTISENSE INHIBITION OF MULTIDRUG RESISTANCE IN CANCER	NCI	1R41CA068790-01	DEAN, NICHOLAS M	1995	$99,865
SYNTHESIS AND SELECTION OF PLA2 INHIBITORS	NIAMS	1R43AR043034-01A1	WYATT, JACQUELINE R	1995	$99,732
UTILITY OF CARBOCYCLIC NUCLEOSIDES FOR ANTISENSE THERAPY	NCI	1R43CA074636-01	GRIFFEY, RICHARD H	1997	$100,000

TARGETING AN ESSENTIAL METHYLASE IN PATHOGENIC BACTERIA	NIAID	1R41AI041775-01A1	BLYN, LAWRENCE B	1998	$99,939
TARGETING RHO--A TRANSCRIPTION TERMINATION FACTOR	NIAID	1R43AI043102-01	BLYN, LAWRENCE B	1998	$100,000
UTILITY OF CARBOCYCLIC NUCLEOSIDES FOR ANTISENSE THERAPY	NCI	3R43CA074636-01S1	GRIFFEY, RICHARD H	1998	$90,000
L11/23S RRNA INTERACTION--ANTIMICROBIAL DRUG DEVELOPMENT	NIAID	1R43AI045210-01	BLYN, LAWRENCE B	1999	$100,000
DISRUPTION OF EUBACTERIAL 4.5S RNA -P48 COMPLEX	NIAID	1R43AI044544-01A1	GRIFFEY, RICHARD H	1999	$100,000
TARGETING 4.5S RNA ANTIMICROBIAL DRUG DISCOVERY	NIAID	1R41AI044515-01	JAMES, THOMAS L	1999	$100,000
ANTISENSE THERAPY USING NOVEL RNA MIMETICS	NIGMS	1R43GM058974-01	MANOHARAN, MUTHIAH	1999	$140,000
OLIGONUCLEOTIDES FOR DIRECTED GENE KNOCKOUT	NIGMS	1R43GM060087-01	MANOHARAN, MUTHIAH	1999	$224,700
ORAL ANTISENSE THERAPY FOR CANCER	NCI	1R41CA083543-01	MANOHARAN, MUTHIAH	2000	$123,990
A NOVEL ANTICANCER STRATEGY	NCI	1R43CA083601-01A1	SAMPATH, RANGARAJAN	2000	$100,000
COMBINATORIAL CARBOHYDRATE LIBRARIES FOR DRUG DISCOVERY	NIAID	1R41AI050406-01	GRIFFEY, RICHARD H	2001	$100,000
ANTIMICROBIAL AGENTS DIRECTED AGAINST L11/23S RRNA	NIAID	2R44AI045210-02A1	SWAYZE, ERIC E	2001	$265,000
ANTIMICROBIAL AGENTS DIRECTED AGAINST L11/23S RRNA	NIAID	5R44AI045210-03	SWAYZE, ERIC E	2002	$375,000
AUTOMATED SIMULTANEOUS DETECTION OF BIOTERRORISM AGENTS	CID	1R01CI000099-01	ECKER, DAVID J	2003	$2,629,242
AUTOMATED SIMULTANEOUS DETECTION OF BIOTERRORISM AGENTS	CID	5R01CI000099-02	ECKER, DAVID J	2004	$2,313,198
SINGLE WELL MPCR DONOR SCREEN TO ID BLOOD PATHOGENS	NHLBI	1R43HL076946-01	RANKEN, RAYMOND	2004	$94,040

PATHOGEN DIAGNOSTIC PRODUCTS--BIODEFENSE DEVELOPMENTS	NIAID	1UC1AI067232-01	BLYN, LAWRENCE B	2005	$4,649,863
AUTOMATED SIMULTANEOUS DETECTION OF BIOTERRORISM AGENTS	CID	5R01CI000099-03	ECKER, DAVID J	2005	$1,036,103
CHEMICAL MODIFICATION TO IMPROVE SIRNA PHARMACOKINETICS IN ANIMALS	NIGMS	1R43GM076793-01	SWAYZE, ERIC E	2006	$99,187
IDENTIFICATION OF AN INHIBITOR OF MICRORNA-122 IN LIVER	NIAID	1R43AI072802-01	FREIER, SUSAN M.	2007	$299,390
CHEMICAL MODIFICATIONS TO IMPROVE RNAI DRUGS	NIGMS	2R44GM076793-02	SWAYZE, ERIC E	2007	$482,643
IDENTIFICATION OF AN INHIBITOR OF MICRORNA-122 IN LIVER	NIAID	5R43AI072802-02	FREIER, SUSAN M.	2008	$132,885
CHEMICAL MODIFICATIONS TO IMPROVE RNAI DRUGS	NIGMS	5R44GM076793-03	SWAYZE, ERIC E	2008	$464,156
ASSESSING THE SAFETY OF CELL SUBSTRATES AND VACCINE COMPONENTS	NIAID	N01AI40100-5-0-1	SAMPATH, RANGARAJAN	2009	$621,848
CHEMICAL MODIFICATIONS TO IMPROVE RNAI DRUGS	NIGMS	5R44GM076793-04	SWAYZE, ERIC E	2009	$463,365
ASSESSING THE SAFETY OF CELL SUBSTRATES AND VACCINE COMPONENTS	NIAID	N01AI40100-6-0-1	SAMPATH, RANGARAJAN	2010	$500,000

3. *Selected DoD Army and DARPA SBIR and STTR grants*

Grant title	Agency	Type	Year	Amount
TIGER Biosensor for Broad Viral Detection and Genetically Engineered Microbes	DoD, Army	SBIR	2005	$119,663
TIGER Biosensor for Broad Viral Detection and Genetically Engineered Microbes	DoD, Army	SBIR	2007	$728,422
Cells as Hierarchical Dynamic Systems	DoD, DARPA	STTR	1999	$99,000

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 3/14/2017 3:39:41 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Anyone have objection from KEI in 2017

KEI has made public statements that it is objecting to all grants of exclusive licenses and that it does not have enough information to analyze whether NIH is making a good decision re the license and royalties and that it does not have sufficient time to respond. OTT reduced the response time from 60 days to 30 days a few years ago and then Richard reduced this further to use the minimum required response time b5 b5

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, March 14, 2017 11:22 AM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Re: Anyone have objection from KEI in 2017

I was asking in general about IRP notices of intent to grant. KEI objected to nearly every notice of exclusive licenses from the IRP last year, and asked for our justification under the statutory criteria for granting the exclusive.

Sent from my iPhone

> On Mar 14, 2017, at 10:29 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:
>
> I am not familiar with this FR notice. I will check. When was the FR notice? Ann
>
>
> -----Original Message-----
> From: Rohrbaugh, Mark (NIH/OD) [E]
> Sent: Monday, March 13, 2017 5:00 PM
> To: NIH TDC Long <niaaatdcl-l@mail.nih.gov>
> Subject: Anyone have objection from KEI in 2017
>
> From FR notice of intent to grant?
>
> Thx
> Mark
>
> Sent from my iPhone

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/25/2019 11:46:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
CC: Goldstein, Bruce (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]
Subject: Emailing: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf, NIHtoKEI re MTTI 25Aug2019.docx
Attachments: KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf; NIHtoKEI re MTTI 25Aug2019.docx

Dale and Mark -- a pdf with KEI's comments (received Aug 23) and a word doc with my response enclosed. Please have a look at both and let me know if you have any comments or edits to the response.

Thanks again!

Regards,

Michael A. Shmilovich, Esq., CLP

Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@mail.nih.gov

This message may contain privileged and confidential information intended only for the use of the individual(s) or entity named above. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, or copying of this message or its content is strictly prohibited. If you have received this message in error, please notify sender immediately and destroy the message without making a copy. Thank you.

"Always be yourself….unless you can be a pyrate… then; obviously, be a pyrate"

Your message is ready to be sent with the following file or link attachments:

KEI Comments NIH License to MTTI Described in 84 FR 39001_.pdf
NIHtoKEI re MTTI 25Aug2019.docx

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

August 23, 2019

Michael Shmilovich, Esq.
Senior Licensing and Patent Manager
National Heart, Lung, and Blood Institute
31 Center Drive
Bethesda, MD 20892

Re: Prospective Grant of Exclusive Patent License: Radiotherapeutic against Cancers that Overexpress Integrin αvβ3, 84 FR 39001

Dear Mr. Shmilovich:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) are writing to comment on the prospective grant of an exclusive patent license in “a radiotherapeutic against cancers that overexpress integrin αvβ3” to Molecular Targeting Technologies, Inc. (MTTI), as referenced in the notice located at 84 FR 39001.

The 84 FR 39001 notice is the third time since 2018 that the NIH has published a notice concerning an exclusive license with MTTI in the same patent family, but it adds a new field of use.

The previous exclusive license and a proposed amendment between the NIH and MTTI for Lutetium-177 technologies were:

- The prospective license noticed on July 27, 2018 (83 FR 35663), which described a prospective exclusive license to MTTI in “Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors,” and
- A prospective amendment to the 2018 license noticed on June 17, 2019 (84 FR 28063), for “Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors.”

KEI filed comments in both of these cases, and copies of those comments are available here: https://www.keionline.org/nih-licenses. The July 2, 2019 comments were filed jointly with the Union for Affordable Cancer Treatment (UACT), and three individuals in their personal capacity, James Love, Manon Ress and Luis Gil Abinader. We ask that the comments regarding the earlier licenses be included in the record for this license, by reference, and also that the suggestions for safeguards in that license that were set forth in the July 2, 2019 comments be considered here for the new license (see below).

The Subject Invention and Patent Estate

Thank you for answering several of our questions about this new license.

Per your answers, it is our understanding that the original licensing opportunity was published in 2015 and updated in 2016, as "early stage."

> Long Acting Therapeutic Conjugates with Evans Blue
> https://www.ott.nih.gov/technology/e-143-2015

The licensing opportunity notice describes the patent estate as "a platform technology that pertains to the advantages of conjugating therapeutics to Evans Blue thus providing long lasting pharmacokinetic profiles by complexing with albumin."

You have described this as a new license that expands the field of use for the same patent estate identified in 84 FR 28063. In your August 23, 2019 email, you compare the new license to the previous MTTI/lu-177 license and its proposed amendment as follows:

> The fields of use and cancer targets are different. The targeting moiety in the previous field of use licensed to the company is tetraazacyclododecanetetraacetic acid-octreotide (TATE) which binds to somatostatin receptor present on neuroendocrine tumors. The targeting moiety in the instant contemplated field is the RGD peptide arginylglycylaspartic acid which binds to integrin avB3 that is overexpressed on a variety of different cancers; however, the present field of use would be limited to only glioblastoma multiforme and small cell lung cancers.

In the event that the NIH decides to grant this exclusive license, we ask that safeguards be placed on the license to protect the public from (a) unreasonable pricing, (b) excessive terms of exclusivity, (c) to address access in developing countries, and (d) to enhance transparency. Our specific suggestions for safeguards are listed below, following further discussion of the licensee.

MTTI

Molecular Targeting Technologies, Inc. (MTTI) appears to be a small privately held firm with few employees of its own, that has considerable success in obtaining NIH grants, either directly or indirectly through non-profit institutions. According to the NIH RePORTER database, MTTI has received funding from the FDA and/or the NIH every year since 1998.

Table 1: NIH RePORTER figures for MTTI grant funding by fiscal year

Fiscal Year	Projects	Total Funding
1995	1	$98,500
1998	1	$100,000
1999	1	$134,600
2000	1	$100,000
2001	1	$372,700
2002	2	$727,300
2003	2	$513,688
2004	1	$335,239
2005	1	$418,825
2006	2	$891,387
2007	3	$1,853,974
2008	3	$1,732,733
2009	6	$1,891,013
2010	2	$572,812
2011	1	$414,018
2012	3	$1,457,619
2013	2	$1,078,417
2014	2	$1,055,660
2015	1	$224,819
2017	2	$514,163
2018	2	$279,610
2019	2	$608,921
Total	42	$15,375,998

MTTI has also benefited from NIH grants to other institutions. For example, MTTI has received NIH funds through grants to Thomas Jefferson University and other research institutions.

The MTTI web page has a list of eight pipeline projects: http://www.mtarget.com/PIPE.html.

Of the eight projects, seven report funding from the NIH. The only project without NIH funding reports funding from the government of Taiwan.

NAME: Rabies mAb	**NAME: ZAPS SN-38**
IP: MTTI licensed from the Thomas Jefferson University North China Pharmaceutical Company (NCPC) is initiating the phase III clinical trial in China in 2018. PARTNER : MTTI sublicensed the product to North China Pharmaceutical Company in exchange for future	INDICATION: Cancer STAGE OF DEVELOPMENT: Phase I clinical planned by Taivex Pharmaceutical in 2019. PARTNER: National Health Research Institutes (NHRI, Taiwan) for preclinical studies.

royalty stream. NCPC is responsible for all clinical development costs.
IP: MTTI licensed from the Thomas Jefferson University
FUNDING: $425,000 from USDA (2006); $918,000 from NIH (2007).
OWNERSHIP: MTTI shares co-exclusive rights in China with Johnson & Johnson (previously Crucell).
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20Rabies%20mAb.pdf

NAME: 177Lu-DOTA-EB-TATE (EBTATE)

INDICATION: Neuroendocrine Neoplasms (NEN)
PROOF OF CONCEPT: Extensive preclinical and two Phase I studies (50 patients) performed by NIH and Peking Union Medical College Hospital (China)
PRINCIPAL COLLABORATORS: NIH & Memorial Sloan Kettering Medical Center
OWNERSHIP: MTTI awarded world-wide-exclusive rights by NIH.
http://www.mtarget.com/mm5/pdfs/pipeline/MTTI%20Asset%20EBTATE.pdf

NAME: 131I SapC-DOPS

INDICATION: Glioblastoma (Brain Cancer)
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: University of Cincinnati
IP: Pending
FUNDING: Obtained funding from NCI.
OWNERSHIP: MTTI is establishing an option agreement with University of Cincinnati
http://www.mtarget.com/mm5/pdfs/pipeline/Glioblastoma.pdf

NAME: LeishCure

INDICATION: Cutaneous Leishmaniasis (CL)
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: University of Notre Dame (UND)
IP: Multiple approved and pending patents on Zn-DPA: US7,179,616; 8,389,223 and 9,211,349.
FUNDING: Obtained funding from NIAID.
OWNERSHIP: MTTI/UND
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20LeishCure.pdf

IP: MTTI/NHRI US Patent 9,388,193B2 July 12, 2016
OWNERSHIP: MTTI/NHRI sublicensed ZAPS technology to Taivex Pharmaceutical
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20ZAPS%20-%20SN%2038.pdf

NAME: AMISCAN

The company has completed a Phase II study funded by NHLBI to assess the ability of 99mTcglucarate to detect cardiac ischemia in chest pain patients.
http://www.mtarget.com/mm5/pdfs/pipeline/AMISCANjan2018March.pdf

NAME: TDURA

CLASS: Imaging Agent
INDICATIONSancer, injury due to drug toxicity, atherosclerotic plaque and acute myocardial infarction
STAGE OF DEVELOPMENT: Ready for Phase 0/1 development in 2018. Seeking partner.
PRINCIPAL COLLABORATOR: University of Antwerp MICA (Molecular Imaging Center Antwerp)
IP: US 7,877,783 B2, US 8,778,303B2, Chinese patent CN102014970B, European approved 2017. These patents are secure through 2029 in US, EU and China. MTTI obtained an exclusive license from the Medical College of Wisconsin.
FUNDING: Obtained ~$1 million non-dilutive grants from NIH & EU.
OWNERSHIP: MTTI
http://www.mtarget.com/mm5/pdfs/pipeline/TDURA.pdf

NAME: CypH

CLASS: Diagnostic Spray for Guided Surgery
INDICATION: Ovarian cancer surgery
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: Cornell Medical College
IP: Pending patents owned by Methodist Hospital, Houston, Texas
FUNDING: Secured funding from NCI
OWNERSHIP: MTTI is establishing an option agreement with Methodist Hospital
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20CypH.pdf

Further Issues Related to the License

Ownership. When the public grants a monopoly on a taxpayer-funded invention, there should be much greater transparency in the process. This transparency should extend to the ownership of the entity seeking an exclusive license. In the United States, publicly-traded companies are required to disclose major shareholders. We ask that the NIH obtain and provide to the public information about who owns any privately-held companies seeking exclusive licenses from the NIH. Related to this issue is the question of foreign ownership. A company can be incorporated in the United States, but have foreign ownership. In our experience, the NIH does not identify or at least does not disclose the ownership of privately-held companies seeking exclusive licenses on taxpayer-funded inventions.

Government role in funding future development. If there is any expectation that the NIH will provide future funding to further develop the technology, that information should be disclosed to the public, and taken into account in negotiating the term of exclusivity in the license. If the U.S. government will be funding any human subject clinical trials relevant to the new license, the period of exclusivity should be reduced to reflect the need for a smaller incentive.

Terms of the proposed license. In recent years, the NIH has refused to describe the term of exclusivity or the royalty rate for a proposed license. Both the royalty rate and the number of years of exclusivity are quite important in evaluating if the NIH is protecting the public interest. We note that in 2018, the NIH reported a mere $118 million in royalty payments for all licenses (https://www.ott.nih.gov/reportsstats/ott-statistics). For the license at hand, we requested the expected royalty rate and statistical data on past licenses for cancer diagnostics and cancer therapeutics, and the NIH declined to provide such information (which we assume the NIH has readily available. The NIH also declined to specifically confirm the expected term of exclusivity, although there was a strong suggestion that the NIH always grants life-of-patent licenses, despite the statutory requirement to limit the scope of each individual license to that which is reasonably necessary to induce investments.

Expected Development Costs. The NIH needs to have an estimate of the expected costs of bringing a technology to practical application, in order to assist in the evaluation of the number of years of exclusivity and other elements of the scope of rights granted.

You have been very helpful in answering several questions about the technology to be licensed. The NIH needs to be more open about the terms of the license, beyond the field of use, and the rationale for the scope of exclusive rights.

In addition to any of the points discussed above, we ask that going forward the NIH provide the following information to the public so that comments on the license can be better informed:

(1) The specific countries where exclusive rights will be licensed;
(2) An estimate of the public expenditures on research and development associated with the inventions to be licensed;
(3) The proposed term of exclusivity for the license;
(4) The proposed royalty;
(5) The expected cost of bringing the invention to practical application;
(6) The measures proposed to ensure the inventions will be made available to the public on reasonable terms;
(7) The measures proposed to ensure access to the inventions in developing countries;
(8) The anticipated non-patent exclusive rights or other incentives associated with the development of the inventions, such as the Orphan Drug Act exclusivity or the Priority Review Voucher; and
(9) The economic analysis, if any, that was used to determine that exclusive rights were necessary, and if so, how the scope of rights, including the term of the exclusive rights, was limited to that which is a reasonably necessary incentive in order to bring the invention to practical application.

Proposals for Additional Safeguards

1. **Price discrimination.** Any drug or other medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

3. **Global registration and affordability.** The license should require Molecular Targeting Technologies, Inc, to disclose the steps it will take to enable the timely registration and availability of the drug or other medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the drug or other medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the drug or other medical technology.

5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

Sincerely,

Knowledge Ecology International
Union for Affordable Cancer Treatment

National Heart, Lung,
and Blood Institute

Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
Michael Shmilovich, Esq, CLP
shmilovm@mail.nih.gov

August 25, 2019

James Packard Love
Luis Gil Abinader
Dr. Manon Anne Ress

IN RE: Prospective Grant of Exclusive Patent License: Radiotherapeutic against Cancers that overexpress Integrin αvβ3
84 FR 39001 (to Molecular Targeting Technologies, Inc. (MTTI)).

Dear Messrs. Love, Abinader and Dr. Ress:

b5

Sincerely,

Misha

Michael A. Shmilovich, Esq., CLP

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/23/2019 10:16:56 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Goldstein, Bruce (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]
Subject: Fwd: Prospective Grant of Exclusive Patent License: Radiotherapeutic against Cancers that Overexpress Integrin αvβ3, 84 FR 39001
Attachments: KEI Comments, NIH License to MTTI, Described in 84 FR 39001 .pdf

Kei's letter regarding my fr notice enclosed. It appears to only be comments that includes their standard boiler plate. b5

From: "James Love" <james.love@keionline.org>
Date: Friday, August 23, 2019 at 16:16:14
To: "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
Cc: "Kathryn Ardizzone" <kathryn.ardizzone@keionline.org>, "Manon Ress" <MANON.RESS@cancerunion.org>, "Luis Gil Abinader" <luis.gil.abinader@keionline.org>, "Claire Cassedy" <claire.cassedy@keionline.org>
Subject: Re: Prospective Grant of Exclusive Patent License: Radiotherapeutic against Cancers that Overexpress Integrin αvβ3, 84 FR 39001

Michael Shmilovich, Esq.
Senior Licensing and Patent Manager
National Heart, Lung, and Blood Institute
31 Center Drive
Bethesda, MD 20892

Comments from KEI and UACT are attached.

--
James Love. Knowledge Ecology International
U.S. Mobile +1.202.361.3040
U.S. office phone +1.202.332.2670
http://www.keionline.org
twitter.com/jamie_love

KNOWLEDGE ECOLOGY INTERNATIONAL

1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

August 23, 2019

Michael Shmilovich, Esq.
Senior Licensing and Patent Manager
National Heart, Lung, and Blood Institute
31 Center Drive
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Re: Prospective Grant of Exclusive Patent License: Radiotherapeutic against Cancers that Overexpress Integrin αvβ3, 84 FR 39001

Dear Mr. Shmilovich:

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- A prospective amendment to the 2018 license noticed on June 17, 2019 (84 FR 28063), for "Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors."

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> The fields of use and cancer targets are different. The targeting moiety in the previous field of use licensed to the company is tetraazacyclododecanetetraacetic acid-octreotide (TATE) which binds to somatostatin receptor present on neuroendocrine tumors. The targeting moiety in the instant contemplated field is the RGD peptide arginylglycylaspartic acid which binds to integrin avB3 that is overexpressed on a variety of different cancers; however, the present field of use would be limited to only glioblastoma multiforme and small cell lung cancers.

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The MTTI web page has a list of eight pipeline projects: http://www.mtarget.com/PIPE.html.

Of the eight projects, seven report funding from the NIH. The only project without NIH funding reports funding from the government of Taiwan.

NAME: Rabies mAb IP: MTTI licensed from the Thomas Jefferson University North China Pharmaceutical Company (NCPC) is initiating the phase III clinical trial in China in 2018. PARTNER : MTTI sublicensed the product to North China Pharmaceutical Company in exchange for future	**NAME: ZAPS SN-38** INDICATION: Cancer STAGE OF DEVELOPMENT: Phase I clinical planned by Taivex Pharmaceutical in 2019. PARTNER: National Health Research Institutes (NHRI, Taiwan) for preclinical studies.

royalty stream. NCPC is responsible for all clinical development costs.
IP: MTTI licensed from the Thomas Jefferson University
FUNDING: $425,000 from USDA (2006); $918,000 from NIH (2007).
OWNERSHIP: MTTI shares co-exclusive rights in China with Johnson & Johnson (previously Crucell).
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20Rabies%20mAb.pdf

NAME: 177Lu-DOTA-EB-TATE (EBTATE)

INDICATION: Neuroendocrine Neoplasms (NEN)
PROOF OF CONCEPT: Extensive preclinical and two Phase I studies (50 patients) performed by NIH and Peking Union Medical College Hospital (China)
PRINCIPAL COLLABORATORS: NIH & Memorial Sloan Kettering Medical Center
OWNERSHIP: MTTI awarded world-wide-exclusive rights by NIH.
http://www.mtarget.com/mm5/pdfs/pipeline/MTTI%20Asset%20EBTATE.pdf

NAME: 131I SapC-DOPS

INDICATION: Glioblastoma (Brain Cancer)
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: University of Cincinnati
IP: Pending
FUNDING: Obtained funding from NCI.
OWNERSHIP: MTTI is establishing an option agreement with University of Cincinnati
http://www.mtarget.com/mm5/pdfs/pipeline/Glioblastoma.pdf

NAME: LeishCure

INDICATION: Cutaneous Leishmaniasis (CL)
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: University of Notre Dame (UND)
IP: Multiple approved and pending patents on Zn-DPA: US7,179,616; 8,389,223 and 9,211,349.
FUNDING: Obtained funding from NIAID.
OWNERSHIP: MTTI/UND
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20LeishCure.pdf

IP: MTTI/NHRI US Patent 9,388,193B2 July 12, 2016
OWNERSHIP: MTTI/NHRI sublicensed ZAPS technology to Taivex Pharmaceutical
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20ZAPS%20-%20SN%2038.pdf

NAME: AMISCAN

The company has completed a Phase II study funded by NHLBI to assess the ability of 99mTcglucarate to detect cardiac ischemia in chest pain patients.
http://www.mtarget.com/mm5/pdfs/pipeline/AMISCANjan2018March.pdf

NAME: TDURA

CLASS: Imaging Agent
INDICATIONSancer, injury due to drug toxicity, atherosclerotic plaque and acute myocardial infarction
STAGE OF DEVELOPMENT: Ready for Phase 0/1 development in 2018. Seeking partner.
PRINCIPAL COLLABORATOR: University of Antwerp MICA (Molecular Imaging Center Antwerp)
IP: US 7,877,783 B2, US 8,778,303B2, Chinese patent CN102014970B, European approved 2017. These patents are secure through 2029 in US, EU and China. MTTI obtained an exclusive license from the Medical College of Wisconsin.
FUNDING: Obtained ~$1 million non-dilutive grants from NIH & EU.
OWNERSHIP: MTTI
http://www.mtarget.com/mm5/pdfs/pipeline/TDURA.pdf

NAME: CypH

CLASS: Diagnostic Spray for Guided Surgery
INDICATION: Ovarian cancer surgery
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: Cornell Medical College
IP: Pending patents owned by Methodist Hospital, Houston, Texas
FUNDING: Secured funding from NCI
OWNERSHIP: MTTI is establishing an option agreement with Methodist Hospital
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20CypH.pdf

Further Issues Related to the License

Ownership. When the public grants a monopoly on a taxpayer-funded invention, there should be much greater transparency in the process. This transparency should extend to the ownership of the entity seeking an exclusive license. In the United States, publicly-traded companies are required to disclose major shareholders. We ask that the NIH obtain and provide to the public information about who owns any privately-held companies seeking exclusive licenses from the NIH. Related to this issue is the question of foreign ownership. A company can be incorporated in the United States, but have foreign ownership. In our experience, the NIH does not identify or at least does not disclose the ownership of privately-held companies seeking exclusive licenses on taxpayer-funded inventions.

Government role in funding future development. If there is any expectation that the NIH will provide future funding to further develop the technology, that information should be disclosed to the public, and taken into account in negotiating the term of exclusivity in the license. If the U.S. government will be funding any human subject clinical trials relevant to the new license, the period of exclusivity should be reduced to reflect the need for a smaller incentive.

Terms of the proposed license. In recent years, the NIH has refused to describe the term of exclusivity or the royalty rate for a proposed license. Both the royalty rate and the number of years of exclusivity are quite important in evaluating if the NIH is protecting the public interest. We note that in 2018, the NIH reported a mere $118 million in royalty payments for all licenses (https://www.ott.nih.gov/reportsstats/ott-statistics). For the license at hand, we requested the expected royalty rate and statistical data on past licenses for cancer diagnostics and cancer therapeutics, and the NIH declined to provide such information (which we assume the NIH has readily available. The NIH also declined to specifically confirm the expected term of exclusivity, although there was a strong suggestion that the NIH always grants life-of-patent licenses, despite the statutory requirement to limit the scope of each individual license to that which is reasonably necessary to induce investments.

Expected Development Costs. The NIH needs to have an estimate of the expected costs of bringing a technology to practical application, in order to assist in the evaluation of the number of years of exclusivity and other elements of the scope of rights granted.

You have been very helpful in answering several questions about the technology to be licensed. The NIH needs to be more open about the terms of the license, beyond the field of use, and the rationale for the scope of exclusive rights.

In addition to any of the points discussed above, we ask that going forward the NIH provide the following information to the public so that comments on the license can be better informed:

(1) The specific countries where exclusive rights will be licensed;
(2) An estimate of the public expenditures on research and development associated with the inventions to be licensed;
(3) The proposed term of exclusivity for the license;
(4) The proposed royalty;
(5) The expected cost of bringing the invention to practical application;
(6) The measures proposed to ensure the inventions will be made available to the public on reasonable terms;
(7) The measures proposed to ensure access to the inventions in developing countries;
(8) The anticipated non-patent exclusive rights or other incentives associated with the development of the inventions, such as the Orphan Drug Act exclusivity or the Priority Review Voucher; and
(9) The economic analysis, if any, that was used to determine that exclusive rights were necessary, and if so, how the scope of rights, including the term of the exclusive rights, was limited to that which is a reasonably necessary incentive in order to bring the invention to practical application.

Proposals for Additional Safeguards

1. **Price discrimination.** Any drug or other medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”

3. **Global registration and affordability.** The license should require Molecular Targeting Technologies, Inc, to disclose the steps it will take to enable the timely registration and availability of the drug or other medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the drug or other medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the drug or other medical technology.

5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

Sincerely,

Knowledge Ecology International
Union for Affordable Cancer Treatment

From: Rodriguez, Richard (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=RODRIQUR]
Sent: 3/14/2017 6:37:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Anyone have objection from KEI in 2017

No I haven't. I thought they had just stopped when I hadn't heard any TTMs mentioning them.

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, March 14, 2017 1:36 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: Re: Anyone have objection from KEI in 2017

I asked your folks here at AUTM and I hear back from Dave and Jim. No one seems to have gotten the exclusive license objections from KEI in 2017 that they were getting last year. Have you heard anything different?

Sent from my iPhone

> On Mar 14, 2017, at 12:17 PM, Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov> wrote:
>
> Hi Mark,
>
> I'm not sure what you are specifically asking for here but you might get a more complete response if you also send this to the ELCG email group. I'm not sure everyone doing licensing is on the NIH Long list.
>
> Richard
>
> -----Original Message-----
> From: Rohrbaugh, Mark (NIH/OD) [E]
> Sent: Monday, March 13, 2017 5:00 PM
> To: NIH TDC Long <niaaatdcl-l@mail.nih.gov>
> Subject: Anyone have objection from KEI in 2017
>
> From FR notice of intent to grant?
>
> Thx
> Mark
>
> Sent from my iPhone

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/23/2019 1:07:02 PM
To: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

Dale – can't explain in a sentence. I'll try to come up with a response and send your way to look through.

From: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Sent: Friday, August 23, 2019 9:00 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: FW: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

b5 Can you explain the situation to me in a sentence or two? I'll try to help with a response.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Sent: Friday, August 23, 2019 8:27 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: Fwd: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

Dale- b5 Let me know what you think i should do

From: "kathryn ardizzone" <kathryn.ardizzone@keionline.org>
Date: Friday, August 23, 2019 at 06:35:50
To: "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>, "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
Cc: "James Love" <james.love@keionline.org>
Subject: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

Dear Mr. Shmilovich:

In light of the upcoming deadline to submit comments, please respond to the following questions as soon as practicable.

1. What is the relationship between the subject technology and the technology covered by the recent past licenses to MTTI (described in 83 FR 35663 and 84 FR 28063)?

2. KEI understands that the 84 FR 28063 license amended the license that resulted from 83 FR 35663. Please confirm that the license in the instant notice would be an additional, separate license and not an amendment.

3. What is the relationship between the **intellectual property** in the present license notice and the previous license/amendment to MTTI?

4. What is the relationship between the **field of use** of the license and the previous license/amendment to MTTI. For example, the previous licenses pertained to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors." The current notice pertains to radiotherapeutic against cancers that overexpress integrin αvβ3, including small cell lung cancers. Neuroendocrine tumors may include small cell lung cancers. **Are the small cell lung cancers that would be targeted by the subject technology neuroendocrine tumors? Does the new field of use expand or does it modify the previous fields of use to MTTI?**

5. Has the NIH, NHLBI, or any institute of the NIH ever published, online, a licensing opportunity notice for the subject invention? If so, where is it located?

6. What are the clinical trial numbers that pertain to the instant technology? How much did the trials cost?

7. Has the NIH sought the advice of the Attorney General under 40 U.S.C. § 559? If not, has it considered the potential anti-competitive effect of the license?

8. What is the NIH's rationale for giving additional IP rights to a company that is already obligated to commercialize the technology under the previous licensing agreement?

9. How and why has the NIH determined that the prospective license would comply with Section 209 of the Bayh Dole Act?

Thank you,

--
Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Baden, Elizabeth (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BADENEM]
Sent: 3/14/2017 4:13:02 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Baden, Elizabeth (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Badenem]
Subject: RE: edits to the Drug Pricing BRAIN brief

Hi Mark,

Thanks so much for the quick feedback. I've incorporated the relevant info in the BRAIN record. I have one more question. b5

b5

Best,
Elizabeth

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, March 13, 2017 6:46 PM
To: Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov>
Subject: Re: edits to the Drug Pricing BRAIN brief

The quick feedback I have gotten is that KEI has not filed objections in at least 2 notices this CY

Sent from my iPhone

On Mar 13, 2017, at 4:17 PM, Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov> wrote:

> Hi Mark,
>
> Thanks for the information below. b5 b5 I moved one bullet that may have caused that comment, and also rearranged the key points b5
>
> If you have a chance, please look at the attached version. My changes are tracked. If this look ok to you, then I can make the changes in BRAIN.
>
> Thanks!
> Elizabeth
>
> ---
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Monday, March 13, 2017 6:02 AM
> **To:** Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>
> **Cc:** Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov>
> **Subject:** Re: edits to the Drug Pricing BRAIN brief
>
> b5

KEI said last year it would appeal to the new HHS Sec'y on Xtandi, and they continue to object to proposed exclusive licensing of specific technologies when public notice is made in FR. Pricing and exclusivity is a current public issue with the Army's proposed Zika vaccine and NIAID is likely to get the same heat when they get to a point of licensing theirs.

With drug pricing issues continuing to fester and comments from the administration about addressing the high price of drugs, we are likely to see more pressure at least from advocacy groups on this issue.

In terms of what we lead with, b5
b5

Sent from my iPhone

On Mar 12, 2017, at 8:49 PM, Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov> wrote:

> Hi Mark,
>
> Dr. Tabak has made the following comment on the Drug Pricing BRAIN brief:
>
> b5
>
> Any chance you can make these changes tomorrow (Monday)? Dr. Collins will be starting his study of the briefs on Monday, so we need to wrap everything up by then.
>
> Thanks,
>
> Marina

<Drug Pricing_v2.docx>

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 8/23/2019 2:39:30 PM
To: Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

See my proposed changes in red below.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

From: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Sent: Friday, August 23, 2019 9:31 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

Dale –please comment. My responses are in blue

From: "kathryn ardizzone" <kathryn.ardizzone@keionline.org>
Date: Friday, August 23, 2019 at 06:35:50
To: "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>, "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
Cc: "James Love" <james.love@keionline.org>
Subject: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

Dear Mr. Shmilovich:

In light of the upcoming deadline to submit comments, please respond to the following questions as soon as practicable.

1. What is the relationship between the subject technology and the technology covered by the recent past licenses to MTTI (described in 83 FR 35663 and 84 FR 28063)?

b5

2. KEI understands that the 84 FR 28063 license amended the license that resulted from 83 FR 35663. Please confirm that the license in the instant notice would be an additional, separate license and not an amendment.

b5

3. What is the relationship between the **intellectual property** in the present license notice and the previous license/amendment to MTTI?

b5

4. What is the relationship between the **field of use** of the license and the previous license/amendment to MTTI. For example, the previous licenses pertained to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors." The current notice pertains to radiotherapeutic against cancers that overexpress integrin αvβ3, including small cell lung cancers. Neuroendocrine tumors may include small cell lung cancers. **Are the small cell lung cancers that would be targeted by the subject technology neuroendocrine tumors? Does the new field of use expand or does it modify the previous fields of use to MTTI?**

b5

5. Has the NIH, NHLBI, or any institute of the NIH ever published, online, a licensing opportunity notice for the subject invention? If so, where is it located?
https://www.ncbi.nlm.nih.gov/pubmed/30506043
https://www.ncbi.nlm.nih.gov/pubmed/27879373
https://patents.google.com/patent/WO2017196806A1/en?oq=PCT%2fUS2017%2f031696 (published November 16, 2017)
https://www.ott.nih.gov/technology/e-143-2015

6. What are the clinical trial numbers that pertain to the instant technology? How much did the trials cost?

b5

7. Has the NIH sought the advice of the Attorney General under 40 U.S.C. § 559? If not, has it considered the potential anti-competitive effect of the license?

b5

8. What is the NIH's rationale for giving additional IP rights to a company that is already obligated to commercialize the technology under the previous licensing agreement?

b5

9. How and why has the NIH determined that the prospective license would comply with Section 209 of the Bayh Dole Act?

b5

Thank you,

--
Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/23/2019 3:11:19 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
Subject: RE: Other response to KEI

Mark- lets discuss when you return. As of this morning I received not less than 4 emails from Kathryn and James Love with questions, many of which were technical and straight forward that I felt comfortable answering. I'll forward those to you.

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, August 23, 2019 11:08 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: Other response to KEI

Where are we with the other response I was going to send. If we agree on language I can send it this morning.

b5 No response needed now

Sent from my iPhone

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 3/14/2018 7:53:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Request for Investigation Re Failure to Disclose Federal Funding in Patent No. 7,964,580
Attachments: HHS-Azar-KEI-Patent-7964580-SOF-14March2018.pdf

Mark: I have not read through completely and as far as I know this has not be assigned to Dr. Collins.

Ann

From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Tuesday, March 13, 2018 1:05 PM
To: secretary@hhs.gov
Cc: Levinson, Dan R (OIG/IO) <dan.levinson@oig.hhs.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Request for Investigation Re Failure to Disclose Federal Funding in Patent No. 7,964,580

Dear Secretary Azar:

Attached, please find a copy of a request that you initiate an investigation into the failure to disclose federal funding leading to the development of Patent No. 7,964,580, held by Gilead. This patent is the first patent listed for Gilead's sofosbuvir and its other sofusbuvir-based treatments for the hepatitis C virus.

As we describe in further detail in the letter, the failure to disclose is a violation of the law under the Bayh-Dole Act and permits the government to receive title to the invention. If a violation is found, we urge you to seek this remedy.

We request a meeting to discuss this matter with you at your earliest convenience.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/23/2019 12:22:32 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]
Subject: Fwd: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

b5 Let me know what you think is best

From: "kathryn ardizzone" <kathryn.ardizzone@keionline.org>
Date: Friday, August 23, 2019 at 06:35:50
To: "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>, "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
Cc: "James Love" <james.love@keionline.org>
Subject: Additional questions about the technology in the proposed exclusive license described in the 84 FR 39001 Notice

Dear Mr. Shmilovich:

In light of the upcoming deadline to submit comments, please respond to the following questions as soon as practicable.

1. What is the relationship between the subject technology and the technology covered by the recent past licenses to MTTI (described in 83 FR 35663 and 84 FR 28063)?

2. KEI understands that the 84 FR 28063 license amended the license that resulted from 83 FR 35663. Please confirm that the license in the instant notice would be an additional, separate license and not an amendment.

3. What is the relationship between the **intellectual property** in the present license notice and the previous license/amendment to MTTI?

4. What is the relationship between the **field of use** of the license and the previous license/amendment to MTTI. For example, the previous licenses pertained to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors." The current notice pertains to radiotherapeutic against cancers that overexpress integrin αvβ3, including small cell lung cancers. Neuroendocrine tumors may include small cell lung cancers. **Are the small cell lung cancers that would be targeted by the subject technology neuroendocrine tumors? Does the new field of use expand or does it modify the previous fields of use to MTTI?**

5. Has the NIH, NHLBI, or any institute of the NIH ever published, online, a licensing opportunity notice for the subject invention? If so, where is it located?

6. What are the clinical trial numbers that pertain to the instant technology? How much did the trials cost?

7. Has the NIH sought the advice of the Attorney General under 40 U.S.C. § 559? If not, has it considered the potential anti-competitive effect of the license?

8. What is the NIH's rationale for giving additional IP rights to a company that is already obligated to commercialize the technology under the previous licensing agreement?

9. How and why has the NIH determined that the prospective license would comply with Section 209 of the Bayh Dole Act?

Thank you,

--
Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From:	Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent:	8/23/2019 3:20:04 PM
To:	Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject:	FW: 84 FR 39001

...These...

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Friday, August 23, 2019 9:45 AM
To: James Love <james.love@keionline.org>
Subject: RE: 84 FR 39001

I do not have information regarding their investors and that information is confidential.

From: James Love <james.love@keionline.org>
Sent: Friday, August 23, 2019 8:38 AM
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: Re: 84 FR 39001

Thank you. So the three different licenses all involve Lu-177, but are different also, in ways the require the separate licenses.

I noticed the lead researcher is from China, was is the founder of Molecular Targeting Technologies, Inc. (MTTI), and that there have been trials in China. Do you know who the investors are in MTTI? For example, is this a company with Chinese investors?

Jamie

On Fri, Aug 23, 2019 at 8:25 AM Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov> wrote:

> Not related. Different tumor, different targeting molecule.
>
> **From:** "James Love" <james.love@keionline.org>
> **Date:** Thursday, August 22, 2019 at 16:27:42
> **To:** "kathryn ardizzone" <kathryn.ardizzone@keionline.org>
> **Cc:** "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
> **Subject:** Re: 84 FR 39001
>
> Dear Michael, is this trial related to the technology in the proposed license?
>
> https://clinicaltrials.gov/ct2/show/record/NCT03478358?term=eb-tate&rank=2
>
> On Wed, Aug 21, 2019 at 5:15 PM James Love <james.love@keionline.org> wrote:
>
>> In terms of the royalty data, if the technology is expected to be used for a therapeutic use, the statistical data on licenses should be for licenses involving therapeutics for cancer.

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 8/23/2019 3:21:09 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: 84 FR 39001

....and this rather odd one, b5 b5

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Friday, August 23, 2019 9:44 AM
To: James Love <james.love@keionline.org>
Subject: RE: 84 FR 39001

I don't have access to that information, you are free to contact the company if they are willing to divulge that information.

From: James Love <james.love@keionline.org>
Sent: Friday, August 23, 2019 9:35 AM
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: Re: 84 FR 39001

As far as we can tell, the NIH is funding every single one of MTTI's pipeline products. Is there an account of how much money the NIH is providing for each of these projects? And more importantly for this license, how much the NIH conducted or funded trials cost?

Jamie

MTTI Pipeline. http://www.mtarget.com/PIPE.html

NAME: Rabies mAb
IP: MTTI licensed from the Thomas Jefferson University
North China Pharmaceutical Company (NCPC) is initiating the phase III clinical trial in China in 2018.
PARTNER : MTTI sublicensed the product to North China Pharmaceutical Company in exchange for
future royalty stream. NCPC is responsible for all clinical development costs.
IP: MTTI licensed from the Thomas Jefferson University
FUNDING: $425,000 from USDA (2006); $918,000 from NIH (2007).
OWNERSHIP: MTTI shares co-exclusive rights in China with Johnson & Johnson (previously Crucell)
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20Rabies%20mAb.pdf

NAME: 177Lu-DOTA-EB-TATE (EBTATE)
INDICATION: Neuroendocrine Neoplasms (NEN)
PROOF OF CONCEPT: Extensive preclinical and two Phase I studies (50 patients) performed by
NIH and Peking Union Medical College Hospital (China).
PRINCIPAL COLLABORATORS: NIH & Memorial Sloan Kettering Medical Center

NAME: ZAPS SN-38
INDICATION: Cancer
STAGE OF DEVELOPMENT: Phase I clinical planned by Taivex Pharmaceutical in 2019.
PARTNER: National Health Research Institutes (NHRI, Taiwan) f preclinical studies.
IP: MTTI/NHRI US Patent 9,388,193B2 July 12, 2016
OWNERSHIP: MTTI/NHRI sublicensed ZAPS technology to Taiv Pharmaceutical
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20ZAPS%20-%20SN%2038.pdf

NAME: AMISCAN
The company has completed a phase II study funded by NHLBI t assess the ability of 99mTcglucarate to detect cardiac ischemia i pain patients.
http://www.mtarget.com/mm5/pdfs/pipeline/AMISCANjan2018Ma

NAME: TDURA
CLASS: Imaging Agent
INDICATION: cancer, injury due to drug toxicity, atherosclerotic p and acute myocardial infarction

OWNERSHIP: MTTI awarded world-wide-exclusive rights by NIH.
http://www.mtarget.com/mm5/pdfs/pipeline/MTTI%20Asset%20EBTATE.pdf

NAME: 131I SapC-DOPS
INDICATION: glioblastoma (brain cancer)
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: University of Cincinnati
IP: pending
FUNDING: Obtained funding from NCI.
OWNERSHIP: MTTI is establishing an option agreement with University of Cincinnat
http://www.mtarget.com/mm5/pdfs/pipeline/Glioblastoma.pdf

NAME: LeishCure
INDICATION: Cutaneous Leishmaniasis (CL)
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: University of Notre Dame (UND)
IP: Multiple approved and pending patents on Zn-DPA: US7,179,616; 8,389,223 and 9,211,349.
FUNDING: Obtained funding from NIAID.
OWNERSHIP: MTTI/UND
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20LeishCure.pdf

STAGE OF DEVELOPMENT: Ready for Phase 0/1 development
2018. Seeking partner.
PRINCIPAL COLLABORATOR: University of Antwerp MICA (Mol
Imaging Center Antwerp)
IP: US 7,877,783 B2, US 8,778,303B2, Chinese patent
CN102014970B, European approved 2017. These
patents are secure through 2029 in US, EU and China. MTTI obta
an exclusive license from the
Medical College of Wisconsin.
FUNDING: Obtained ~$1 million non-dilutive grants from NIH & E
OWNERSHIP: MTTI
http://www.mtarget.com/mm5/pdfs/pipeline/TDURA.pdf

NAME: CypH
CLASS: Diagnostic Spray for Guided Surgery
INDICATION: Ovarian cancer surgery
STAGE OF DEVELOPMENT: Preclinical. Seeking partner.
PRINCIPAL COLLABORATOR: Cornell Medical College
IP: Pending patents owned by Methodist Hospital, Houston, Texa
FUNDING: Secured funding from NCI
OWNERSHIP: MTTI is establishing an option agreement with Me
Hospital
http://www.mtarget.com/mm5/pdfs/pipeline/Asset%20CypH.pdf

From: Joe Allen [jallen@allen-assoc.com]
Sent: 3/13/2018 3:07:56 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]
Subject: KEI using King language, misrepresentation of march in rights in letter to USTR on compulsory licenses

Of course, Bayh-Dole has never been used as implied in the highlighted paragraph below, but why let facts get in the way of a good story:

(https://www.keionline.org/27147)

KEI testimony at March 8, 2018 USTR Special 301 hearing, focusing on US compulsory licensing of patents

Posted on March 8, 2018 by James Love

On March 8, 2018, USTR and the interagency committee on the Special 301 held a hearing. KEI was one of the groups testifying. More on this process here: https://keionline.org/ustr/special301

I began our oral testimony discussing President Trump's promise, during the election, to negotiate lower prices on drugs for Medicare, noting that many of the comments by PhRMA and other drug company lobby groups would create norms that would make it impossible for President Trump to deliver on even a small fraction of his promised savings.

I then read the following comments about compulsory licensing.

(more on compulsory licensing here: https://keionline.org.cl)

Compulsory licensing

PhRMA and other groups lobbying on behalf of big drug companies frequently target the use of compulsory licensing as a "harmful IP-related trade barrier".

KEI sees compulsory licenses as an important and underutilized tool to address excessive pricing and restrictive licensing practices.

I would like to take a minute to provide some context for this proceeding.

First, the United States has at least 15 separate statutes that are used to permit non-voluntary use of patents, not counting our various exceptions to patent rights for research or uses by medical professionals.

Second, the United States is by far, and I mean by far, the most frequent user of compulsory licenses. USTR itself overturned an injunction on the importation of iPhones and iPads that infringed on patents owned by Samsung, on August 3, 2013.[1]

Under the Supreme Court eBay Doctrine regarding the enforcement on injunctions, courts routinely permit infringement of patents, when royalties are paid to the patent holder. For another example involving Apple: in 2017, Apple successfully asked a judge for permission to use, without a voluntary license but subject to an ongoing royalty, U.S. Patent No. 5,781,752, titled "Table based data speculation circuit for parallel processing computer.[2]

The compulsory licenses under the eBay doctrine are fairly common, about one a month for a while, but now less frequent as parties tend to grant voluntary licenses, when it is perceived to be hard to enforce an injunction, and they cover a wide range of technologies.

In the area of medical technologies, the most common compulsory licenses ordered by the courts are for medical devices and diagnostics, of which there are many, on everything from contact lenses to artificial heart valves to diagnostic technologies. Often the companies requesting such compulsory license are innovators themselves.

For example, in 2008, Abbott used the eBay doctrine to obtain a license to HCV Genotyping testing patents. Similar compulsory licensing efforts were successful in several high income countries, including Germany, where Roche was requesting the compulsory license, and in Australia and the UK, to mention a few other countries.

The United States has also used the threat of compulsory licensing to force more liberal licensing or price discounts, in cases where the federal government was a funder of research, including the patents on reverse genetics needed to manufacture vaccines for the Avian flu, the stem cell patents held by WARF, the Abbott patents on ritonavir, and the Fabry patents now held by Sanofi, to mention a few cases under the Bayh-Dole Act. In 2016, 51 members of Congress asked the federal government to make more frequent use of this Act.[3]

Recently 18 members of Congress asked the federal government to use 28 USC 1498 to grant compulsory licenses on patents on HCV drugs, and the Senate Armed Services Committee in 2017 adopted a directive to the Department of Defense to use compulsory licenses when prices on Army-funded drugs like Xtandi are more expensive in the United States than in other high income countries.

Many persons, including President Trump, have called for changes in the law to allow Medicare to negotiate drug prices. If Medicare negotiates drug prices, it will involve a threat, by the United States, to withhold reimbursement, narrow formularies or increase co-payments. All of these measures hurt patients. We want the Congress to give the government more robust authority to use compulsory licensing, in order to protect patients, effectively putting the monopoly at risk rather than the patient, when there are disputes over prices.

KEI and others are planning to asking the Trump administration to use, under existing statutes, either or both 35 USC 203 and/or 28 USC 1498, to end monopolies, on at least three drugs, this calendar year. In every case there are very significant abuses of patent rights, and negative consequences for patients.

Finally, we want to call attention to the growing patent thickets for two new important technologies, CRISPR and CAR T. If we don't have to ability to use compulsory licenses to force more liberal licensing of technologies, it will harm innovation and make us defenseless from abusive pricing.

[1] Michael Froman's decision in the Apple/Samsung ITC patent dispute and the USTR trade agenda, August 6, 2013, https://www.keionline.org/22282.

[2] Wisconsin Alumni Research Foundation v. Apple, Inc., Case: 3:14-cv-00062-wmc, (W.D. Wis., June 6, 2017).

[3] 2016: 51 members of Congress have asked the NIH to use March-In rights to rein in high drug prices, January 11, 2016. https://www.keionline.org/22983

Annex. US statutes that are used for compulsory licensing (non-voluntary use) of patents.

35 U.S.C. 203 – MARCH-IN RIGHTS (Bayh-Dole Act)
35 U.S.C. 271(e)(6)(B) – INFRINGEMENT OF PATENT (biologic products where patents are not timely disclosed)
35 U.S.C. 283 – INJUNCTION (under eBay doctrine)

28 USC 1498 – Patent and copyright cases (use by or for government)

30 U.S.C. 937 – CONTRACTS AND GRANTS (Black Lung disease)

42 USC Sec 2183 – Nonmilitary utilization (patents on atomic energy)
42 U.S.C. 7608 – MANDATORY LICENSING (Clean Air Act)
42 U.S.C. 16192 – NEXT GENERATION LIGHTING INITIATIVE
42 U.S.C. 17231 – ENERGY STORAGE COMPETITIVENESS

19 U.S.C. 1337 – UNFAIR PRACTICES IN IMPORT TRADE (United States International Trade Commission)

Sherman Antitrust Act, 15 USC 1-7
15 U.S. Code § 1 – Trusts, etc., in restraint of trade illegal; penalty
15 U.S. Code § 2 – Monopolizing trade a felony; penalty

Wilson Tariff Act, 15 USC 8-11
15 U.S. Code § 8 – Trusts in restraint of import trade illegal; penalty

Clayton Act, 15 USC 12-27

15 U.S.C. 45 – UNFAIR METHODS OF COMPETITION UNLAWFUL; PREVENTION BY COMMISSION (Federal Trade Commission)

Access to Medicine, Trade Compulsory Licensing, Special 301, USTR

James Love

James Love is the Director of Knowledge Ecology International. Previously, he was an economist for the Center for Study of Responsive Law where he also directed the Consumer Project on Technology and the Taxpayer Assets Project, Senior Economist for the Frank Russell Corporation, and held lecturer positions at Rutgers and Princeton Universities. His KEI webpage is https://keionline.org/jamie.

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Innogenetics v. Abbott – 2008 compulsory license granted for HCV genotyping kits under eBay v. MercExchange

Chile Ministry of Health Takes Next Step Toward Compulsory License on HCV Drugs, Announces Public Health Justifications

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Joseph P. Allen
President
Allen and Associates
60704 Rt. 26, South
Bethesda, OH 43719
(W) 740-484-1814
(c) 304-280-2259
www.allen-assoc.com

From: Baden, Elizabeth (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BADENEM]
Sent: 3/13/2017 8:17:12 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Volkov, Marina (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=nimh/cn=mvolkov]
Subject: RE: edits to the Drug Pricing BRAIN brief
Attachments: Drug Pricing_v2.docx

Hi Mark,

Thanks for the information below. b5 b5 I moved one bullet that may have caused that comment, and also rearranged the key points b5

If you have a chance, please look at the attached version. My changes are tracked. If this look ok to you, then I can make the changes in BRAIN.

Thanks!
Elizabeth

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, March 13, 2017 6:02 AM
To: Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>
Cc: Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov>
Subject: Re: edits to the Drug Pricing BRAIN brief

b5

KEI said last year it would appeal to the new HHS Sec'y on Xtandi, and they continue to object to proposed exclusive licensing of specific technologies when public notice is made in FR. Pricing and exclusivity is a current public issue with the Army's proposed Zika vaccine and NIAID is likely to get the same heat when they get to a point of licensing theirs.

With drug pricing issues continuing to fester and comments from the administration about addressing the high price of drugs, we are likely to see more pressure at least from advocacy groups on this issue.

In terms of what we lead with, b5 b5

Sent from my iPhone

On Mar 12, 2017, at 8:49 PM, Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov> wrote:

> Hi Mark,
>
> Dr. Tabak has made the following comment on the Drug Pricing BRAIN brief:
>
> b5
>
> Any chance you can make these changes tomorrow (Monday)? Dr. Collins will be starting his study of the briefs on Monday, so we need to wrap everything up by then.

Thanks,

Marina

b5

b5

b5

b5

b5

b5

b5

b5

From: Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]
Sent: 2/28/2018 10:14:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Gottesman, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=918c2344931542a592d00dbe83d3d5a3-gottesmm]
Subject: FW: ES - WF 370674 - FYI (CC)

Hi Mark – Since you mentioned this in our meeting this morning, I wanted to make sure that you were aware of this DDRMS notice. Looks like it has been assigned to NCI to respond. Regards, Karen

Karen L. Rogers
Acting Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

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From: EDRMS_NO_REPLY@mail.nih.gov [mailto:EDRMS_NO_REPLY@mail.nih.gov]
Sent: Wednesday, February 28, 2018 3:29 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; White, Tracy (NIH/OD) [E] <whitever@od.nih.gov>; White, Tracy (NIH/OD) [E] <whitever@od.nih.gov>
Subject: ES - WF 370674 - FYI (CC)

To whom it may concern:

Message from the Director's Document and Records Management System (DDRMS)

You have received a task notification requiring your attention.

Please do not reply to this email, this is an automated message.

If you have concerns please contact the NIH Help Desk at (301) 496-4357.

Work Folder Information
Work Folder: WF 370674

Process: FYI
Program Analyst: Cramer, Lindsay (NIH/OD) [E]
Due Date:
WF Subject: Mr. Andrew Goldman writes to Dr. David Lambertson (NCI) and Dr. Collins to provide Knowledge Ecology International's (KEI) appeal of the NIH/NCI decision to proceed with the anti-CD30 license to Kite Pharma. This email is in response to Dr. Lambertson's February 26 email responding to KEI's February 14 email requesting information on the formal appeal procedures.
IC: od_ott
From: Goldman, Andrew
To: Lambertson, DavidCollins, Francis
Remarks: FYI to OER, OIR, OTT, and OGC. Assigned to NCI for any necessary action. Thank you! -Lindsay

Additional instructions are included on the task form, click the link to open the Task

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 2/27/2018 9:12:51 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Jambou, Robert (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff42a9fa39824980aa9e36af49e56cbc-jambour]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
Subject: RE: FOIA Request -- Can you help?

Mark—sorry for the delay. b5
b5

Best, Dale

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, February 27, 2018 2:00 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Jambou, Robert (NIH/OD) [E] <jambour@od.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>
Subject: RE: FOIA Request -- Can you help?

Dale:

b5

See below.

THanks,
Mark

From: Jambou, Robert (NIH/OD) [E]
Sent: Tuesday, February 27, 2018 1:45 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>
Subject: RE: FOIA Request -- Can you help?

OK thank you Mark.

b5

Thanks so much!

Bob J.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, February 27, 2018 1:37 PM
To: Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Jambou, Robert (NIH/OD) [E] <jambour@od.nih.gov>
Subject: RE: FOIA Request -- Can you help?

b5

From: Jorgenson, Lyric (NIH/OD) [E]
Sent: Tuesday, February 27, 2018 1:32 PM
To: Jambou, Robert (NIH/OD) [E] <jambour@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: FOIA Request -- Can you help?

I'm meeting with CW in an hour. I'll make sure to bring it up with her as well. Mark – do you have a recommendation?

b5

From: Jambou, Robert (NIH/OD) [E]
Sent: Tuesday, February 27, 2018 1:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>
Subject: FOIA Request -- Can you help?

Hi Mark & Lyric,

We have received a FOIA request from Andrew S. Goldman of Knowledge Ecology International (KEI -- see items attached "Request for documents for OSP request" and therein "Request 47590.pdf"). The formal request consists of four aggregated requests.

The instructions from the FOIA office per Roger Bordine – b5
b5

Any guidance you can provide on how to proceed with this request would be greatly appreciated.

Thanks…

Bob J.

From: Jambou, Robert (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FF42A9FA39824980AA9E36AF49E56CBC-JAMBOUR]
Sent: 2/27/2018 6:27:30 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
Subject: FOIA Request -- Can you help?
Attachments: Request for documents for OSP request

Hi Mark & Lyric,

We have received a FOIA request from Andrew S. Goldman of Knowledge Ecology International (KEI -- see items attached "Request for documents for OSP request" and therein "Request 47590.pdf"). The formal request consists of four aggregated requests.

The instructions from the FOIA office per Roger Bordine – b5
b5

Any guidance you can provide on how to proceed with this request would be greatly appreciated.

Thanks...

Bob J.

From: Sullivan, Nicholle (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=49A1E4D7663F48A39B2D953804DDBFB8-SULLIVANN]
Sent: 2/26/2018 8:37:30 PM
To: Jambou, Robert (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff42a9fa39824980aa9e36af49e56cbc-jambour]
Subject: Request for documents for OSP request
Attachments: NIH FOIA Request for Direct - Goldman (OSP) - (Aggregate 4 requests into 1 request).pdf; Request 47590.pdf

Flag: Follow up

Hi Bob,

We received the attached FOIA Requests for any and all documents seeking antitrust advice under 40 USC section 559 for specified date ranges: 1) January 1, 2000 to the present; 2) the year 1979; 3) the year 1984 and 4) the year 1994from the period of January 1, 1979 to December 31, 1979. 40 U.S.C. § 559 concerns the obligation of Federal Agencies to seek and obtain antitrust advice from the Attorney General prior to the disposal of property, including patents, to private interests.

The requester is specifically interested in any documents which discuss the obligations of NIH, including any of its institutes and centers, with regard to seeking antitrust advice in the context of licensing federally-owned and/or federally-funded inventions.

The FOIA requests will be aggregated into one OSP request per the attached email. Please conduct a search for responsive records and if you could, please give me an idea of how the search is going.

Thanks so much,

Nicholle

Nicholle Sullivan, J.D.
Lead Government Information Specialist
Freedom of Information and Privacy Act Branch OM/OD/NHLBI
6705 Rockledge Dr., Suite 6054
Bethesda, MD 20892-7957
301-496-9737 (office)
240-507-9935 (direct line)
301-402-3604 (fax)
sullivann@mail.nih.gov

From: Bordine, Roger (NIH/OD) [E]
To: NHLBI FOIA REQUEST (NIH/NHLBI)
Cc: Manheim, Marianne (NIH/NHLBI) [E]; NIH FOIA
Subject: NIH FOIA Request for Direct - Goldman (OSP) - (Aggregate 4 requests into 1 request)
Date: Thursday, February 22, 2018 12:21:00 PM
Attachments: 2369_001.pdf
image001.png

Good Afternoon,

Please see the attached request for direct response regarding a copy of records related to the NIH's obligation to seek anti-trust advice from the Attorney General regarding federally owned or funded inventions.

b5

Thank you.

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov

Goldman

DATE: 2/22/2018

TO: **Marianne Manheim**
NHLBI FOIA Coordinator
Building Rockledge 1, Rm. 6182
6705 Rockledge Drive
Bethesda, MD 20892

FROM: NIH FOIA Office, OD/OCPL

SUBJECT: FOIA Log No. 2018/052

The attached FOIA request is forwarded to you for the following action:

FOR DIRECT REPLY. Enter the case into the FOIA Tracking System. Upon completion, please complete the Close-Out, and if there is an invoice, please send a copy of the invoice with the final letter to the NIH FOIA Office.

If you forward this request to a program office within your IC, keep a copy of this request in your FOIA Case file. As the IC FOIA Coordinator, you are responsible for the collection of records and follow-up until the request is closed.

Please contact the NIH FOIA Office on 301-496-5633 or at nihfoia@mail.nih.gov if you have any questions.

COMMENTS: See Email (OSP)

From:	Andrew Goldman <andrew.goldman@keionline.org>
Sent:	Wednesday, February 21, 2018 1:05 PM
To:	NIH FOIA
Subject:	Re: FOIA Request Re: NIH Seeking Antitrust Advice Under 40 U.S.C. § 559
Attachments:	KEI_FOIA21Feb2018_NIH_40_USC_559.pdf; KEI_FOIA21Feb2018_NIH_40_USC_559_2.pdf; KEI_FOIA21Feb2018_NIH_40_USC_559_3.pdf; KEI_FOIA21Feb2018_NIH_40_USC_559_4.pdf

Dear Sir or Madam:

Yesterday I sent four related FOIA requests, but I unfortunately attached the incorrect requests. If you could please replace those requests with the corrected versions attached, I would appreciate it.

Best,
Andy

RECEIVED
FEB 21 2018
NIH
FOIA OFFICE

2018/052

--
Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

On Tue, Feb 20, 2018 at 12:51 PM, Andrew Goldman <andrew.goldman@keionline.org> wrote:

> Dear Sir or Madam:
>
> Please find attached four related Freedom of Information Act requests from Knowledge Ecology International regarding the NIH's obligations to seek antitrust advice under 40 USC § 559. The first is for the period January 1, 2000 to the present; the second is for the year of 1979; the third is for the year of 1984; and the fourth is for the year of 1994.
>
> Thank you in advance for your attention to this request.
>
> Sincerely,
>
> Andrew S. Goldman
> Counsel, Policy and Legal Affairs
> Knowledge Ecology International
> andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
> tel.: +1.202.332.2670
> www.keionline.org

FROM: Andrew S. Goldman
c/o Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
andrew.goldman@keionline.org

RECEIVED
FEB 21 2018
NIH
FOIA OFFICE

2018/052

TO: FOIA Officer
FOIA Information Office
NIH Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
nihfoia@mail.nih.gov

DATE: February 21, 2018

RE: Freedom of Information Act Request Regarding NIH Seeking Antitrust Advice Under 40 U.S.C. § 559

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant NIH regulations (45 CFR Part 5), Knowledge Ecology International (KEI) requests any and all documents, from the period of January 1, 1979 to December 31, 1979, related to 40 U.S.C. § 559.

40 U.S.C. § 559 concerns the obligation of Federal Agencies to seek and obtain antitrust advice from the Attorney General prior to the disposal of property, including patents, to private interests.

We are specifically interested in any documents which discuss the obligations of NIH, including any of its institutes and centers, with regard to seeking antitrust advice in the context of licensing federally-owned and/or federally-funded inventions.

Request for Full Waiver of Fees

Knowledge Ecology International (KEI) requests a full waiver of fees under the Freedom of Information Act and under 45 CFR Part 5.54.

KEI is a 501(c)(3) non-profit organization that promotes the public interest in ensuring equitable access to affordable medicines.

Congress enacted the current FOIA fee waiver provisions to protect the interests of non-profit public interest groups, such as KEI, that seek to disseminate information that is in the public interest:

> "The waiver provision was added to FOIA 'in an attempt to prevent government agencies from using high fees to discourage certain types of requesters and requests,' in a clear reference to requests from journalists, scholars and, most importantly for our purposes, nonprofit public interest groups." *Better Gov't Ass'n v. Department of State*, 780 F.2d 86, 94 (D.C. Cir. 1986) (citations omitted).

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government.

1. § 5.54(b)(1): "Disclosure of the requested information would shed light on the operations or activities of the government."

Disclosure of the requested records would shed light on the operations and activities of the federal government with regards to 40 U.S.C. § 559, particularly with regard to obligations federal agencies have in seeking antitrust advice in the context of licensing federally-owned patents. In evaluating this factor, "reasonable specificity" is "all that FOIA requires." Judicial Watch v. Rossotti , 326 F.3d 1309, 1313 (D.C. Cir. 2003).

2. § 5.54(b)(2): Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities.

This factor is satisfied because the following criteria are met.

2.i. § 5.54(b)(2)(i): Disclosure of the requested records must be meaningfully informative about government operations or activities.

Disclosure of the requested records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain. In particular it would provide information regarding whether the National Institutes of Health is abiding by the law when licensing medical technologies that have received federal funding. This information would be helpful in informing policy discussions regarding the public interest and the disposal of federal property.

As mentioned previously, the information is not publicly available and our attempt to seek that information from the NIH was denied.

"Legislative history suggests that information has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health." McClellan Ecological Seepage Situation v. Carlucci , 835 F.2d 1282, 1286 (9th. Cir. 1987) (citations omitted).

2.i. § 5.54(b)(2)(ii): The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester.

The subject of the request concerns government operations and activities related to the antitrust ramifications of the licensing of federally-owned and federally-funded patents, including on medical technologies, and is intertwined with policy discussions affecting the prices of prescription drugs in the United States.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to federal R&D funding and its approach to drug pricing issues.

KEI is an NGO that works on drug pricing and access to medicines, and has expertise in public health, drug pricing, and access to medicines.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates a website (https://keionline.org) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will review the requested records and produce a clear and concise analysis of those records. KEI will use social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request.

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently on various government operations and activities at parts of DHHS:

- 28 February 2017, "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB," https://keionline.org/node/2727
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- 31 December 2016, Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," Buzzfeed News, https://www.buzzfeed.com/danvergano/nih-drug-giveaway
- 20 December 2016, "Front page New York Times story explores Kite Pharma's profitable relationship with NIH regarding expensive cancer drug," https://keionline.org/node/2703

3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670

andrew.goldman@keionline.org

FROM: Andrew S. Goldman
c/o Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
andrew.goldman@keionline.org

RECEIVED
FEB 21 2018
NIH
FOIA OFFICE

2018/052

TO: FOIA Officer
FOIA Information Office
NIH Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
nihfoia@mail.nih.gov

DATE: February 21, 2018

RE: Freedom of Information Act Request Regarding NIH Seeking Antitrust Advice Under 40 U.S.C. § 559

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant NIH regulations (45 CFR Part 5), Knowledge Ecology International (KEI) requests any and all documents, from the period of January 1, 1984 to December 31, 1984, related to 40 U.S.C. § 559.

40 U.S.C. § 559 concerns the obligation of Federal Agencies to seek and obtain antitrust advice from the Attorney General prior to the disposal of property, including patents, to private interests.

We are specifically interested in any documents which discuss the obligations of NIH, including any of its institutes and centers, with regard to seeking antitrust advice in the context of licensing federally-owned and/or federally-funded inventions.

Request for Full Waiver of Fees

Knowledge Ecology International (KEI) requests a full waiver of fees under the Freedom of Information Act and under 45 CFR Part 5.54.

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Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government.

1. § 5.54(b)(1): "Disclosure of the requested information would shed light on the operations or activities of the government."

Disclosure of the requested records would shed light on the operations and activities of the federal government with regards to 40 U.S.C. § 559, particularly with regard to obligations federal agencies have in seeking antitrust advice in the context of licensing federally-owned patents. In evaluating this factor, "reasonable specificity" is "all that FOIA requires." Judicial Watch v. Rossotti , 326 F.3d 1309, 1313 (D.C. Cir. 2003).

2. § 5.54(b)(2): Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities.

This factor is satisfied because the following criteria are met.

2.i. § 5.54(b)(2)(i): Disclosure of the requested records must be meaningfully informative about government operations or activities.

Disclosure of the requested records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain. In particular it would provide information regarding whether the National Institutes of Health is abiding by the law when licensing medical technologies that have received federal funding. This information would be helpful in informing policy discussions regarding the public interest and the disposal of federal property.

As mentioned previously, the information is not publicly available and our attempt to seek that information from the NIH was denied.

"Legislative history suggests that information has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health." McClellan Ecological Seepage Situation v. Carlucci , 835 F.2d 1282, 1286 (9th. Cir. 1987) (citations omitted).

2.i. § 5.54(b)(2)(ii): The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester.

The subject of the request concerns government operations and activities related to the antitrust ramifications of the licensing of federally-owned and federally-funded patents, including on medical technologies, and is intertwined with policy discussions affecting the prices of prescription drugs in the United States.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to federal R&D funding and its approach to drug pricing issues.

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3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670

andrew.goldman@keionline.org

FROM: Andrew S. Goldman
c/o Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
andrew.goldman@keionline.org

TO: FOIA Officer
FOIA Information Office
NIH Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
nihfoia@mail.nih.gov

RECEIVED
FEB 21 2018
NIH
FOIA OFFICE

2018/052

DATE: February 21, 2018

RE: Freedom of Information Act Request Regarding NIH Seeking Antitrust Advice Under 40 U.S.C. § 559

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant NIH regulations (45 CFR Part 5), Knowledge Ecology International (KEI) requests any and all documents, from the period of January 1, 1994 to December 31, 1994, related to 40 U.S.C. § 559.

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If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670

andrew.goldman@keionline.org

FROM: Andrew S. Goldman
c/o Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
andrew.goldman@keionline.org

RECEIVED
FEB 21 2018
NIH
FOIA OFFICE

2018/052

TO: FOIA Officer
FOIA Information Office
NIH Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
nihfoia@mail.nih.gov

DATE: February 21, 2018

RE: Freedom of Information Act Request Regarding NIH Seeking Antitrust Advice Under 40 U.S.C. § 559

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant NIH regulations (45 CFR Part 5), Knowledge Ecology International (KEI) requests any and all documents, from the period of January 1, 2000 to the present, related to 40 U.S.C. § 559.

40 U.S.C. § 559 concerns the obligation of Federal Agencies to seek and obtain antitrust advice from the Attorney General prior to the disposal of property, including patents, to private interests.

We are specifically interested in any documents which discuss the obligations of NIH, including any of its institutes and centers, with regard to seeking antitrust advice in the context of licensing federally-owned and/or federally-funded inventions.

Request for Full Waiver of Fees

Knowledge Ecology International (KEI) requests a full waiver of fees under the Freedom of Information Act and under 45 CFR Part 5.54.

KEI is a 501(c)(3) non-profit organization that promotes the public interest in ensuring equitable access to affordable medicines.

Congress enacted the current FOIA fee waiver provisions to protect the interests of non-profit public interest groups, such as KEI, that seek to disseminate information that is in the public interest:

> "The waiver provision was added to FOIA 'in an attempt to prevent government agencies from using high fees to discourage certain types of requesters and requests,' in a clear reference to requests from journalists, scholars and, most importantly for our purposes, nonprofit public interest groups." *Better Gov't Ass'n v. Department of State*, 780 F.2d 86, 94 (D.C. Cir. 1986) (citations omitted).

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government.

1. § 5.54(b)(1): "Disclosure of the requested information would shed light on the operations or activities of the government."

Disclosure of the requested records would shed light on the operations and activities of the federal government with regards to 40 U.S.C. § 559, particularly with regard to obligations federal agencies have in seeking antitrust advice in the context of licensing federally-owned patents. In evaluating this factor, "reasonable specificity" is "all that FOIA requires." Judicial Watch v. Rossotti , 326 F.3d 1309, 1313 (D.C. Cir. 2003).

2. § 5.54(b)(2): Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities.

This factor is satisfied because the following criteria are met.

2.i. § 5.54(b)(2)(i): Disclosure of the requested records must be meaningfully informative about government operations or activities.

Disclosure of the requested records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain. In particular it would provide information regarding whether the National Institutes of Health is abiding by the law when licensing medical technologies that have received federal funding. This information would be helpful in informing policy discussions regarding the public interest and the disposal of federal property.

As mentioned previously, the information is not publicly available and our attempt to seek that information from the NIH was denied.

"Legislative history suggests that information has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health." McClellan Ecological Seepage Situation v. Carlucci , 835 F.2d 1282, 1286 (9th. Cir. 1987) (citations omitted).

2.i. § 5.54(b)(2)(ii): The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester.

The subject of the request concerns government operations and activities related to the antitrust ramifications of the licensing of federally-owned and federally-funded patents, including on medical technologies, and is intertwined with policy discussions affecting the prices of prescription drugs in the United States.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to federal R&D funding and its approach to drug pricing issues.

KEI is an NGO that works on drug pricing and access to medicines, and has expertise in public health, drug pricing, and access to medicines.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates a website (https://keionline.org) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will review the requested records and produce a clear and concise analysis of those records. KEI will use social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request.

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3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, “setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched.” 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

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andrew.goldman@keionline.org

National Institutes of Health

Turning Discovery Into Health

Goldman

RECEIVED
21FEB18
OSP 47590
FOIA SERVICE CENTER

DATE: 2/22/2018

TO: **Marianne Manheim**
NHLBI FOIA Coordinator
Building Rockledge 1, Rm. 6182
6705 Rockledge Drive
Bethesda, MD 20892

FROM: NIH FOIA Office, OD/OCPL

SUBJECT: FOIA Log No. 2018/052

The attached FOIA request is forwarded to you for the following action:

FOR DIRECT REPLY. Enter the case into the FOIA Tracking System. Upon completion, please complete the Close-Out, and if there is an invoice, please send a copy of the invoice with the final letter to the NIH FOIA Office.

If you forward this request to a program office within your IC, keep a copy of this request in your FOIA Case file. As the IC FOIA Coordinator, you are responsible for the collection of records and follow-up until the request is closed.

Please contact the NIH FOIA Office on 301-496-5633 or at nihfoia@mail.nih.gov if you have any questions.

COMMENTS: See Email (OSP)

< [redacted] >

Bordine, Roger (NIH/OD) [E]

From: Andrew Goldman <andrew.goldman@keionline.org>
Sent: Wednesday, February 21, 2018 1:05 PM
To: NIH FOIA
Subject: Re: FOIA Request Re: NIH Seeking Antitrust Advice Under 40 U.S.C. § 559
Attachments: KEI_FOIA21Feb2018_NIH_40_USC_559.pdf; KEI_FOIA21Feb2018_NIH_40_USC_559_2.pdf; KEI_FOIA21Feb2018_NIH_40_USC_559_3.pdf; KEI_FOIA21Feb2018_NIH_40_USC_559_4.pdf

Dear Sir or Madam:

Yesterday I sent four related FOIA requests, but I unfortunately attached the incorrect requests. If you could please replace those requests with the corrected versions attached, I would appreciate it.

Best,
Andy

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FEB 21 2018
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FOIA OFFICE

2018/052

--
Andrew S. Goldman
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Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

On Tue, Feb 20, 2018 at 12:51 PM, Andrew Goldman <andrew.goldman@keionline.org> wrote:

Dear Sir or Madam:

Please find attached four related Freedom of Information Act requests from Knowledge Ecology International regarding the NIH's obligations to seek antitrust advice under 40 USC § 559. The first is for the period January 1, 2000 to the present; the second is for the year of 1979; the third is for the year of 1984; and the fourth is for the year of 1994.

Thank you in advance for your attention to this request.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
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3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

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The subject of the request concerns government operations and activities related to the antitrust ramifications of the licensing of federally-owned and federally-funded patents, including on medical technologies, and is intertwined with policy discussions affecting the prices of prescription drugs in the United States.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to federal R&D funding and its approach to drug pricing issues.

KEI is an NGO that works on drug pricing and access to medicines, and has expertise in public health, drug pricing, and access to medicines.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates a website (https://keionline.org) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will review the requested records and produce a clear and concise analysis of those records. KEI will use social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request.

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently on various government operations and activities at parts of DHHS:

- 28 February 2017, "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB," https://keionline.org/node/2727
- 18 October 2016, "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments," https://keionline.org/node/2640
- 19 September 2016, "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies," https://keionline.org/node/2630
- 16 September 2016, "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs," https://keionline.org/node/2629 Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA.

KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories:

- 3 March 2017, Vidya Krishnan, "U.S. nixed India's plea on reforms in medicine," The Hindu,http://www.thehindu.com/news/national/us-nixed-indias-plea-on-reforms-in-medicine/article17403526.ece
- 31 December 2016, Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," Buzzfeed News, https://www.buzzfeed.com/danvergano/nih-drug-giveaway
- 20 December 2016, "Front page New York Times story explores Kite Pharma's profitable relationship with NIH regarding expensive cancer drug," https://keionline.org/node/2703

3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670

andrew.goldman@keionline.org

FROM: Andrew S. Goldman
c/o Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
andrew.goldman@keionline.org

RECEIVED
FEB 21 2018
NIH
FOIA OFFICE

2018/052

TO: FOIA Officer
FOIA Information Office
NIH Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
nihfoia@mail.nih.gov

DATE: February 21, 2018

RE: Freedom of Information Act Request Regarding NIH Seeking Antitrust Advice Under 40 U.S.C. § 559

Dear FOIA Officer:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant NIH regulations (45 CFR Part 5), Knowledge Ecology International (KEI) requests any and all documents, from the period of January 1, 2000 to the present, related to 40 U.S.C. § 559.

40 U.S.C. § 559 concerns the obligation of Federal Agencies to seek and obtain antitrust advice from the Attorney General prior to the disposal of property, including patents, to private interests.

We are specifically interested in any documents which discuss the obligations of NIH, including any of its institutes and centers, with regard to seeking antitrust advice in the context of licensing federally-owned and/or federally-funded inventions.

Request for Full Waiver of Fees

Knowledge Ecology International (KEI) requests a full waiver of fees under the Freedom of Information Act and under 45 CFR Part 5.54.

KEI is a 501(c)(3) non-profit organization that promotes the public interest in ensuring equitable access to affordable medicines.

Congress enacted the current FOIA fee waiver provisions to protect the interests of non-profit public interest groups, such as KEI, that seek to disseminate information that is in the public interest:

> "The waiver provision was added to FOIA 'in an attempt to prevent government agencies from using high fees to discourage certain types of requesters and requests,' in a clear reference to requests from journalists, scholars and, most importantly for our purposes, nonprofit public interest groups." *Better Gov't Ass'n v. Department of State*, 780 F.2d 86, 94 (D.C. Cir. 1986) (citations omitted).

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government.

1. § 5.54(b)(1): "Disclosure of the requested information would shed light on the operations or activities of the government."

Disclosure of the requested records would shed light on the operations and activities of the federal government with regards to 40 U.S.C. § 559, particularly with regard to obligations federal agencies have in seeking antitrust advice in the context of licensing federally-owned patents. In evaluating this factor, "reasonable specificity" is "all that FOIA requires." Judicial Watch v. Rossotti , 326 F.3d 1309, 1313 (D.C. Cir. 2003).

2. § 5.54(b)(2): Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities.

This factor is satisfied because the following criteria are met.

2.i. § 5.54(b)(2)(i): Disclosure of the requested records must be meaningfully informative about government operations or activities.

Disclosure of the requested records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain. In particular it would provide information regarding whether the National Institutes of Health is abiding by the law when licensing medical technologies that have received federal funding. This information would be helpful in informing policy discussions regarding the public interest and the disposal of federal property.

As mentioned previously, the information is not publicly available and our attempt to seek that information from the NIH was denied.

"Legislative history suggests that information has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health." McClellan Ecological Seepage Situation v. Carlucci , 835 F.2d 1282, 1286 (9th. Cir. 1987) (citations omitted).

2.i. § 5.54(b)(2)(ii): The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester.

The subject of the request concerns government operations and activities related to the antitrust ramifications of the licensing of federally-owned and federally-funded patents, including on medical technologies, and is intertwined with policy discussions affecting the prices of prescription drugs in the United States.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to federal R&D funding and its approach to drug pricing issues.

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KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates a website (https://keionline.org) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will review the requested records and produce a clear and concise analysis of those records. KEI will use social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request.

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently on various government operations and activities at parts of DHHS:

- 28 February 2017, "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB," https://keionline.org/node/2727
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- 19 September 2016, "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies," https://keionline.org/node/2630
- 16 September 2016, "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs," https://keionline.org/node/2629 Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA.

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- 3 March 2017, Vidya Krishnan, "U.S. nixed India's plea on reforms in medicine," The Hindu,http://www.thehindu.com/news/national/us-nixed-indias-plea-on-reforms-in-medicine/article17403526.ece
- 31 December 2016, Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," Buzzfeed News, https://www.buzzfeed.com/danvergano/nih-drug-giveaway
- 20 December 2016, "Front page New York Times story explores Kite Pharma's profitable relationship with NIH regarding expensive cancer drug," https://keionline.org/node/2703

3. § 5.54(b)(3): The disclosure must not be primarily in the commercial interest of the requester.

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670

andrew.goldman@keionline.org

From: Pollard, Ricquita (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC946982E43F43CB925773EA52C40AFA-POLLARDRD]
Sent: 8/29/2018 9:58:49 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Chatterjee, Sabarni (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4520fc058d6457aac24b57685235b12-chatterjees]
Subject: RE: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665
Attachments: Response to KEI_comments on A-311-2018_082018.docx

Hi Mark,

Attached please find additional details in the response to KEI. If you have time to discuss over the phone, please let me know.

Thanks,
Ricquita

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, August 21, 2018 4:18 PM
To: Pollard, Ricquita (NIH/NCI) [E] <ricquita.pollard@nih.gov>
Cc: Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>
Subject: RE: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Ricquita: This is a good outline. I would suggest **b5**
b5

Mark

From: Pollard, Ricquita (NIH/NCI) [E]
Sent: Tuesday, August 21, 2018 1:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>
Subject: FW: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Hi Mark,

I am processing a Start-Up Exclusive License application (A-311-2018) from Midissia Therapeutics for a cancer immunotherapy. The *Federal Register* Notice for this application (attached) was posted on July 27th and the comment period according to the notice ended August 13th. I received an email from James Love and Manon Ress on August 13th (see below) with comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) addressing four topics: 1) No discrimination against US residents in pricing, 2) Reduce term of exclusivity when revenues are large, 3) Developing countries, and 4) Transparency.

Please see my proposed response in the attached WORD document. If you have any questions or concerns, please let me know.

Thanks,

Ricquita

Ricquita D. Pollard, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute
9609 Medical Center Drive, Rm 1-E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): (240) 276-5530
Direct Phone: (240) 276-5490
Fax: (240) 276-5503
pollardrd@mail.nih.gov

https://ttc.nci.nih.gov/index.php

Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents.

From: James Love <james.love@keionline.org>
Sent: Monday, August 13, 2018 11:48 PM
To: Pollard, Ricquita (NIH/NCI) [E] <ricquita.pollard@nih.gov>
Subject: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

August 13, 2018

Ricquita Pollard, Technology Transfer Manager,
NCI Technology Transfer Center,
Via Email: pollardrd@mail.nih.gov.

Re: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Dear Ricquita Pollard:

The following are comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT), on the proposed exclusive license for patents noticed in the Federal Register for a license to Midissia Therapeutics ("Midissia") located in San Francisco, California.

1. No discrimination against US residents in pricing

We ask that the NIH include language in the proposed exclusive license to ensure that the prices in the U.S. for any drug, vaccine, medical device or other health technology using the inventions are not higher than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.

We consider this a modest request to protect U.S. residents, who paid for the R&D that created the licensed inventions.

2. Reduce term of exclusivity when revenues are large

In addition to an external reference pricing test, we propose that the exclusivity of the license in the U.S. should be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks.

Given the modest cost of acquiring an NIH patented invention, the amount of money the developer needs in sales to justify additional investments in R&D is reduced, as compared to cases where a company developes or acquires the technology from non government sources.

This request is consistent with the statutory requirements of 35 USC 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

One possible implementation of revenue benchmarks is as follows: exclusivity will be reduced by one year for every $500 million in revenue equivalents, earned after the first $1 billion, where revenue equivalent is defined as global cumulative sales plus market entry rewards as well as government grants or tax credits, for the product or products using the invention. However, the NIH could choose different benchmarks, so long as the limits on exclusivity address the requirements of 35 USC 209, that the incentive is "not greater than reasonably necessary."

3. Developing countries

We are concerned that several NIH funded inventions are not accessible in developing countries, due to prices that are high and not affordable in markets where per capita incomes are significantly lower than the United States. For this reason, we ask the NIH to limit the exclusivity in the license to countries that have per capita incomes that are at least 30 percent of the United States.

We also ask the NIH to reach out to the Medicines Patent Pool (MPP), in order to enter into an agreement that gives the MPP an option to negotiate non-exclusive open licenses for the inventions in developing countries.

4. Transparency

The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 USC 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to market.

Sincerely,

James Love
Knowledge Ecology International

Manon Anne Ress
Union for Affordable Cancer Treatment

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

August 29, 2018

James Love
Scientific and Technical Advisor
Knowledge Ecology International

Manon Anne Ress
Union for Affordable Cancer Treatment

IN RE: Your Letter Dated August 13, 2018 in response to 83 FR 35663, Published July 27, 2018 *"Prospective Grant of Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy"*

Dear James Love and Manon Ress:

b5

b5

Please let me know if you have any questions.

Sincerely,

Ricquita Pollard, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH

From: Wojtowicz, Emma (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45C6610ACA6E44A08D497630425E5ECD-WOJTOWICZEM]
Sent: 7/9/2019 6:12:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Here is the link: https://www.statnews.com/2019/07/09/dc-diagnosis-drug-prices-tv-ads/

Drug pricing advocates put NIH in the hot seat

The drug industry foe Patients For Affordable Drugs has a new report out this morning arguing that taxpayers have contributed at least $300 million toward the development of a gene therapy to cure sickle cell disease — and the group says that's reason enough for the NIH to demand the treatment be reasonably priced.

"Given the $1 to $2 million price range of recent gene therapies, we are concerned that a sickle cell cure will be brought to market at a price that is unaffordable for patients and for the taxpayers who supported its development," the group writes. "The NIH should use all levers in its power to ensure the final price accounts for public investment."

The group has a number of suggestions to NIH on how to establish pricing guardrails, including requiring that the drug maker price the drug at no more than the average of comparable OECD nations.

This isn't the first time drug pricing advocates have railed against NIH licensing out government-developed drugs without restricting what drug makers can charge, but those complaints so far have fallen on deaf ears.

An NIH spokesperson declined to comment on P4AD's pricing concerns and emphasized that NIH does not have a role in setting prices. The spokesperson also disputed P4AD's argument that $300 million went to the development of this one particular therapy, because the NIH studies were foundational research studies. "You can't take foundational studies and apply them to one product," the spokesperson said.

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, July 9, 2019 1:02 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Did the STAT article come out?

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, July 9, 2019 12:59 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

b4

From: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Sent: Tuesday, July 9, 2019 12:55 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Hi Mark-

Did you find out if we have a patent for LentiGlobin BB305? We received another press inquiry and would like to get back to the reporters this afternoon.

Thank you!
Emma

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 8, 2019 3:03 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Yes, I will come up

From: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Sent: Monday, July 8, 2019 3:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Hi Mark-

Are you available at 3:30pm?

Thanks-
Emma

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Monday, July 8, 2019 2:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

The reporter has not responded to me so we will see. Thank you-

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 8, 2019 10:58 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>

Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Anytime after 1? Will that work?

From: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Sent: Monday, July 8, 2019 10:46 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Thanks, Mark. What is your availability?

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 8, 2019 10:45 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: Re: From STAT: Request for comment on upcoming report on NIH research

Yes

Sent from my iPhone

On Jul 8, 2019, at 9:39 AM, Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov> wrote:

> Hi Mark-
>
> I am following up on Amanda's email from Saturday. Let us know if you are available to speak to the reporter before 2pm today.
>
> Thanks-
> Emma
>
> ---
>
> **From:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
> **Sent:** Saturday, July 6, 2019 7:01 AM
> **To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
> **Cc:** Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
> **Subject:** RE: From STAT: Request for comment on upcoming report on NIH research
>
> Thanks Mark. Do you think it would be easier if you got on the phone with him and explained it to him on background?
>
> I'm out Monday, but either Renate or Emma will pick this up.
>
> Hope you have a good weekend,
> Amanda
>
> ---
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
> **Sent:** Friday, July 5, 2019 4:31 PM
> **To:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
> **Cc:** Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
> **Subject:** RE: From STAT: Request for comment on upcoming report on NIH research

b5

From: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Sent: Friday, July 5, 2019 4:02 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: FW: From STAT: Request for comment on upcoming report on NIH research

Hi Mark-

Please see below/attached. b5

b5

b5

Amanda

From: Florko, Nicholas <nicholas.florko@statnews.com>
Sent: Friday, July 5, 2019 3:10 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: From STAT: Request for comment on upcoming report on NIH research

Appreciate you honoring the embargo. It's actually Patients For Affordable Drugs. And it's specifically about the sickle cell gene therapy LentiGlobin BB305. They say taxpayer-funded NIH research has invested more than $300 million into development of the therapy. (See table attached) Do you disagree with this number?

And then they're calling for NIH to impose guardrails on the pricing for the drug, including:
- a commitment from a drug manufacturer – upon acquiring the NIH-supported patent – to limit the U.S. price of a drug to no more than the average of comparable OECD nations.
- a commitment from a drug manufacturer that licensing agreements are contingent on the drug company agreeing to price the drug based on specific metrics. (Metrics could include: Manufacturing costs, royalty payments, clinical trials and R&D as reported to the IRS, and the value of tax credits received in exchange for the drug's development (i.e. orphan drug credits); Amount of money taxpayers invested in the drug; A profit margin based on the company's historic reported profit and loss over a recent five-year period.)

They also suggest creating an outside advisory committee to assist NIH in developing a methodology to determine reasonable prices.

Any chance you all could comment on whether NIH has the ability to impose such restrictions on pricing for these drugs?

My deadline is 2PM Monday.

Thank you!

On Fri, Jul 5, 2019 at 2:36 PM Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Hi Nick-
>
> Thanks for reaching out. Is it KEI? We can honor the embargo. What are your specific questions? We can look into them and do our best to get back to you by your deadline.
>
> Thanks,
> Amanda
>
> Get Outlook for iOS
>
> ---
>
> **From:** Florko, Nicholas <nicholas.florko@statnews.com>
> **Sent:** Friday, July 5, 2019 2:30:46 PM

To: Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
Subject: Fwd: From STAT: Request for comment on upcoming report on NIH research

Hello --

Forwarding the below since Senate is out of the office! Thanks.

---------- Forwarded message ---------
From: **Florko, Nicholas** <nicholas.florko@statnews.com>
Date: Fri, Jul 5, 2019 at 2:22 PM
Subject: From STAT: Request for comment on upcoming report on NIH research
To: <mylesr@mail.nih.gov>

Hi Renate --

I'm a reporter over at STAT. Nice to meet you. I'm writing up an embargoed report set to go out Tuesday from an advocacy group about NIH funding for a potential gene therapy.

I'd like to get NIH's take on both the estimate from the authors on the level of funding taxpayers have invested in the treatment, and the group's calls for there to be guardrails on the price for the drug. I know that's vague, but I wanted to ask before I share more details: Would you be able to honor the 6AM embargo if I share more details with you?

Thanks,
Nick

--
Nick Florko
Washington Correspondent
202-549-4576
@NicholasFlorko

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--
Nick Florko
Washington Correspondent
202-549-4576
@NicholasFlorko

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Washington Correspondent
202-549-4576
@NicholasFlorko

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From: Niebylski, Charles (NIH/NIDDK) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=NIEBYLSKICD]
Sent: 11/2/2016 8:55:48 PM
To: Fine, Amanda (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Fineab]; Ano, Susan (NIH/NINDS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ANOS]; Rodriguez, Richard (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=RODRIQUR]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Chang, Kevin (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=RECIPIENTS/cn=CHANGKE]; Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]; Wojtowicz, Emma (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wojtowiczeme6d]; NCI Press Officers [/O=NIH/OU=NIHEXCHANGE/cn=NCI/cn=ncipressofficers]
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Hello,

Here is some more information on the CCZ clinical trial that Jake Liang says he is OK with sharing with the press:

> The design of the CCZ trial has been posted on ClinicalTrial.Gov (NCT02118012). The preliminary analysis did not show a significant antiviral effect, probably because of the dose we used (as allowed by the FDA). Detailed analyses are being performed in preparation for a manuscript, which will describe the whole trial, data analyses and outcome.

From: "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
Date: Wednesday, November 2, 2016 at 1:08 PM
To: "Ano, Susan (NIH/NINDS) [E]" <susan.ano@nih.gov>, "Rodriguez, Richard (NIH/NCI) [E]" <richard.rodriguez@nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Niebylski, Charles (NIH/NIDDK) [E]" <niebylskicd@niddk.nih.gov>
Cc: Kevin Chang <changke@mail.nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>, "Wojtowicz, Emma (NIH/OD) [E]" <emma.wojtowicz@nih.gov>, NCI Press Officers <ncipressofficers@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Thank you again for your help on this matter. Mark spoke with Dan earlier and explained generally how and why we use exclusive licenses.

Dan did ask for more information about the Phase 1 clinical trial of which chlorcyclizine was a part. He would like us to confirm that it is/was a Phase 1 trial, what exactly it was for, how chlorcyclizine fit into the trial, and if there are any results we can provide. I believe for that last question someone from this group said that results will be published soon, however it would be good to understand if what is being published will be descriptive of the whole trial or just the outcome of the chlorcyclizine.

Thank you for your continued guidance and input!
Amanda

From: Fine, Amanda (NIH/OD) [E]
Sent: Friday, October 28, 2016 6:11 PM
To: Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>;

Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Sorry for the delay. For your review and input, please see the below draft response:

b5

Thanks!

Amanda

On Oct 28, 2016, at 11:24 AM, Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov> wrote:

There's a typo in the email below. The first statement should read "b5

b5

Best regards,

Sue

Susan Ano, Ph.D.
Technology Development Coordinator
Office of Technology Transfer
The National Institute of Neurological Disorders and Stroke
The National Institutes of Health
Mail address: 31 Center Drive, Suite 8A52, MS2540
Bethesda, MD 20892
Physical location: Bldg. 31, 8A07
phone (301) 435-5515
cell b5

<image001.jpg>

Have patience. All things are difficult before they become easy."
-- Saadi, poet

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:12 AM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

b5

b5

Richard

From: Chang, Kevin (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:08 AM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Richard,

b5

Sue was working on responses to the questions.

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:04 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Amanda,

Just saw this and have attached my response to Chuck. If you have more questions, I'm happy to have a call.

Thanks,

Richard

RICHARD U. RODRIGUEZ, M.B.A.
Associate Director, Technology Transfer Center
Patent Agent

National Cancer Institute
National Institutes of Health
9609 Medical Center Drive, Rm 1E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): 240-276-5530
Direct phone: 240-276-6661
Fax 240-276-5504
richard.rodriguez@nih.gov

https://ttc.nci.nih.gov/index.php

"Change is inevitable. Progress is optional" – Tony Roberts

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From: Chang, Kevin (NIH/NCI) [E]
Sent: Thursday, October 27, 2016 6:26 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News
Importance: High

Hi Amanda,

Chuck has also approached me regarding these questions. Richard, Sue, and Mark may be the best positioned to provide NIH's official responses on these two questions. Richard should be back from travel on Monday but I can chat with Mark if he needs background about this specific license.

When do you need the responses to the questions by?

Best regards,

Kevin

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 5:03 PM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Kevin-

Please see the below long thread about a Buzzfeed inquiry regarding chlorcyclizine as a result of a complaint by Knowledge Ecology International. As you may know, KEI regularly approaches NIH regarding licensing and exercising march-in rights. We are working to set up an interview with Mark next week, however wanted to provide the reporter with some background. He asked a few questions about granting the license that folks said you would know and I was hoping you would help us in drafting responses to these questions. Specifically the following 2 questions:

2) What are the institute's priorities when licensing these drugs?

b5

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Please let me know if you have any questions.

Thank you in advance for your help and input!
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246

Email:amanda.fine@nih.gov
Web:http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 3:42 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Just following up on this to see if there was any progress in drafting responses to Dan's questions. His deadline is tomorrow.

b5

(2) What are the institute's priorities when licensing these drugs?

b5

(3) How much progress has this licensee made on marketing this drug?

You would need to check with the licensee.

(4) What were the results of the Phase 1 trial that NIH funded on this drug?

These will be published in the near future.

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Chuck-were you able to speak to Kevin Chang about this?

Thanks to all in advance for your input and guidance.

Best,
Amanda

b5

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 11:34 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Morning Mark –

You had a bad address for Chuck so I'm adding him in with his NIDDK email.

This is actually for NIDDK to respond as we (OTT) would not feel comfortable answering questions for NIDDK on their licenses. That said, we will certainly assist NIDDK with the information we can find.

Chuck, let's chat on this tomorrow.
Deb

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 10:15 AM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov
Subject: Fwd: Interview request/chlorcyclizine pricing: BuzzFeed News

Deb and Karen:

Could you please help me follow up on this for Amanda and the press inquiry? [redacted] b5

[redacted] b5

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

> **From:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Date:** October 24, 2016 at 9:49:59 PM GMT+1
> **To:** "Niebylski, Charles (NIH/NIDDK) [E]" <niebylskicd@niddk.nih.gov>
> **Cc:** "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
> **Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News**
>
> > Chuck:
> >
> > See thread below. Could you help answer the questions about NIH licensing?
> >
> > Thanks
> > Mark
> >
> > Sent from my iPhone
> >
> > Begin forwarded message:
> >
> > > **From:** "Portilla, Lili (NIH/NCATS) [E]" <portilll@mail.nih.gov>
> > > **Date:** October 24, 2016 at 9:22:01 PM GMT+1
> > > **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Vepa, Sury (NIH/NCATS) [E]" <sury.vepa@nih.gov>
> > > **Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News**
> > >
> > > Mark:

NIDDK took the lead on this as their PI (Jake Liang) was the biology lead. NCATS has a few co-inventors on the patent who did screening and med chem. The licensing for this was done by OTT specifically Kevin Chang. Chuck Nybeliski was also very involved on the NCATS side when he was part of our office. I would speak to him on this matter in his role as Director of the NIDDK TTO.

Regards,

Lili

Lili M. Portilla, MPA
Director, Office of Strategic Alliances
National Center for Advancing Translational Sciences, NIH
9800 Medical Center Drive, Room 3042
Rockville, MD 20850
Phone: 301-217-2589
Email: Lilip@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:51 PM
To: Driscoll, Claire (NIH/NHGRI) [E] <cdriscol@mail.nih.gov>; Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Sorry Claire, meant to copy Lili

Sent from my iPhone

On Oct 24, 2016, at 8:50 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

> b5
>
> Sent from my iPhone

Begin forwarded message:

From: "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
Date: October 24, 2016 at 8:27:59 PM GMT+1
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: "McBurney, Margaret (NIH/OD) [E]" <mmcburney@od.nih.gov>, "Hardesty, Rebecca (NIH/OD) [C]" <rebecca.hardesty@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>, "Wojtowicz, Emma (NIH/OD) [E]" <emma.wojtowicz@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

b5

b5

Thanks Mark! Hope you're not working while on vacation.

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:22 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: McBurney, Margaret (NIH/OD) [E] <mmcburney@od.nih.gov>; Hardesty, Rebecca (NIH/OD) [C] <rebecca.hardesty@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

I am available. Looks ok to me. Not sure why the email thread was released under FOIA. There is more one could say but this is the basic message. b5

b5

Sent from my iPhone

On Oct 24, 2016, at 8:10 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Greetings-
>
> I'm including all three of you per Mark's out of office and given that the reporter's deadline is October 28.
>
> NIDDK received the below inquiry from Dan Vergano at Buzzfee

d regarding Knowledge Ecology International’s (KEI) questions about the drug chlorcyclizine which had/has a small trial at the CC. Attached is a back and forth with NIDDK/NCATS that KEI got through FOIA. Dan’s questions are below.

b5

b5

b5

b5

Thank you in advance for your input and guidance,

Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email:amanda.fine@nih.gov

Web:http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

From: Payne, January (NIH/NIDDK) [E]
Sent: Monday, October 24, 2016 2:54 PM
To: OCPLPressTeam <OCPLPressTeam@od.nih.gov>; ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Cc: NIDDK NIDDK MEDIA (NIH/NIDDK) <niddkmedia

@niddk.nih.gov>
Subject: Interview request/chlorcyclizine pricing: BuzzFeed News

Hello, NIDDK received an interview request from a Buzzfeed reporter asking about NIH involvement in licensing and drug pricing for chlorcyclizine. Chuck Niebylski, director of NIDDK's Technology Advancement Office, asked that I refer this request to NIH OD as it involves NIH's policy on drug pricing.

Below is the complete email exchange I've had with the reporter, Dan Vergano, and attached is a PDF of an email chain between NIH employees that the reporter received via a public interest group called Knowledge Ecology International, which obtained the records via a FOIA request. (Please note, for background: KEI also published this 2015 post about the same drug.)

Is NIH OD able to respond to this request?

Thank you,
January W. Payne
Office of Communications and Public Liaison
National Institute of Diabetes andDigestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH
Direct 301-435-8115
Cell
b6
Office 301-496-3583
www.niddk.nih.gov
NIH...Turning Discovery Into

Health
®

Celebration of Science at NIH: *Watch how medical research saves lives and improves health*

From: Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 12:29 PM
To: Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov>
Subject: Re: BuzzFeed News: press

contact / licensing

January,

Thanks for getting back to me

-- The drug is chlorcyclizine (link to license annc't below), and the public interest group, Knowledge Ecology International (which often looks at NIH licenses) is complaining that its request for "reasonable pricing" requirements in the license were brushed aside to the detriment of taxpayers. The group has just received a public records request (a portion is attached) and suggests they show that NIH is worried more about scaring off the licensee than benefiting the taxpayers who funded this drug and have no assurance they won't have to pay excessively high prices for it.

-- I'm looking for an agency response to this contention.

-- My deadline is 10/28/16 at 5 PM EDT

-- My questions would basically be:
How do you respond to their

complaint? What are the institute's priorities when licensing these drugs? How much progress has this licensee made on marketing this drug? What were the results of the Phase 1 trial that NIH funded on this drug? Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

I'd have follow-ups depending on the answers, natch, and would want to hear any responses to smarter questions on all this that your folks might have.

Any help appreciated,

Dan Vergano
BuzzFeed News
202 629 4563

Dan Vergano | Science Reporter (DC) | 202 629 4563
BuzzFeed
1630 Connecticut Ave. 7th Floor,

Washington DC 20009

link: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-06974.pdf

Dan Vergano | Science Reporter (DC) | 202 629 4563
BuzzFeed
1630 Connecticut Ave. 7th Floor, Washington DC 20009

On Mon, Oct 24, 2016 at 11:57 AM, Payne, January (NIH/NIDDK) [E] <january.pay

ne@nih.gov> wrote:

> Dear Dan,
>
> Thanks for your message. Can you please provide more information so I can look into your request?
>
> - What is the drug name, and can you please briefly describe the issue that has been raised? Also, what is the name of the public

interest group?

- What is your hard deadline?

- Can you please provide a few examples of questions you'd like to ask?

Best,

January W. Payne

Office of Communications and Public Liaison
National Institute of Diabetes andDigestive and Kidney Diseases

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From: Dan Vergano [mailto:dan.

vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 11:25 AM
To: NIDDK NIDDK MEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Fwd: BuzzFeed News: press contact / licensing

Krysten's email responder suggested I send this note to this contact. I have also left a phone message with the press office. I am looking for comment this week.

Ms. Carrera,

I'm a science reporter at Buzz Feed News. I'm looking for a press contact at NIDDK who can address a drug licensing issue at your institute. A public intere st group is raising questions about one of your licenses and I'd like to get a response from the institute.

Thanks for any help,

Dan Vergano

BuzzFeed News

202/629-4563

Dan Vergano | Scienc

e Reporter (DC) | 202 629 4563 **BuzzFeed** 1630 Connecticut Ave. 7th Floor, Washington DC 20009

JANUARY PAYNE

@ National Institutes of Health

National Institutes of Health | 9000 Rockville Pike, Bethesda, MD 20892, USA | Official
(NIH). NIH is one of the world's foremost medical research centers. An agency of...

January Payne on LinkedIn

@NIH | 663K followers | 6K tweets - 3 hours ago

There's still time to submit your @NIH_LRPapplication! Get started on yours today. bit.ly/2e7QDzt#studentdebt

Search for January Payne on Google

Dan is using Senders. View / edit your own Card

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NIH
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<image001.jpg>

From: Wojtowicz, Emma (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45C6610ACA6E44A08D497630425E5ECD-WOJTOWICZEM]
Sent: 7/8/2019 7:03:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Okay, thank you.

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 8, 2019 3:03 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Yes, I will come up

From: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Sent: Monday, July 8, 2019 3:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Hi Mark-

Are you available at 3:30pm?

Thanks-
Emma

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Monday, July 8, 2019 2:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

The reporter has not responded to me so we will see. Thank you-

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 8, 2019 10:58 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Anytime after 1? Will that work?

From: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Sent: Monday, July 8, 2019 10:46 AM

To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Thanks, Mark. What is your availability?

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, July 8, 2019 10:45 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: Re: From STAT: Request for comment on upcoming report on NIH research

Yes

Sent from my iPhone

On Jul 8, 2019, at 9:39 AM, Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov> wrote:

Hi Mark-

I am following up on Amanda's email from Saturday. Let us know if you are available to speak to the reporter before 2pm today.

Thanks-
Emma

From: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Sent: Saturday, July 6, 2019 7:01 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

Thanks Mark. Do you think it would be easier if you got on the phone with him and explained it to him on background?

I'm out Monday, but either Renate or Emma will pick this up.

Hope you have a good weekend,
Amanda

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, July 5, 2019 4:31 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: RE: From STAT: Request for comment on upcoming report on NIH research

b5

b5

From: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Sent: Friday, July 5, 2019 4:02 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: FW: From STAT: Request for comment on upcoming report on NIH research

Hi Mark-

Please see below/attached. b5

b5

Amanda

From: Florko, Nicholas <nicholas.florko@statnews.com>
Sent: Friday, July 5, 2019 3:10 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: From STAT: Request for comment on upcoming report on NIH research

Appreciate you honoring the embargo. It's actually Patients For Affordable Drugs. And it's specifically about the sickle cell gene therapy LentiGlobin BB305. They say taxpayer-funded NIH research has invested more than $300 million into development of the therapy. (See table attached) Do you disagree with this number?

And then they're calling for NIH to impose guardrails on the pricing for the drug, including:
- a commitment from a drug manufacturer – upon acquiring the NIH-supported patent – to limit the U.S. price of a drug to no more than the average of comparable OECD nations.
- a commitment from a drug manufacturer that licensing agreements are contingent on the drug company agreeing to price the drug based on specific metrics. (Metrics could include: Manufacturing costs, royalty payments, clinical trials and R&D as reported to the IRS, and the value of tax credits received in exchange for the drug's development (i.e. orphan drug credits); Amount of money taxpayers invested in the drug; A profit margin based on the company's historic reported profit and loss over a recent five-year period.)

They also suggest creating an outside advisory committee to assist NIH in developing a methodology to determine reasonable prices.

Any chance you all could comment on whether NIH has the ability to impose such restrictions on pricing for these drugs?

My deadline is 2PM Monday.

Thank you!

On Fri, Jul 5, 2019 at 2:36 PM Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Hi Nick-
>
> Thanks for reaching out. Is it KEI? We can honor the embargo. What are your specific questions? We can look into them and do our best to get back to you by your deadline.
>
> Thanks,
> Amanda
>
> Get Outlook for iOS
>
> ---
>
> **From:** Florko, Nicholas <nicholas.florko@statnews.com>
> **Sent:** Friday, July 5, 2019 2:30:46 PM
> **To:** Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
> **Subject:** Fwd: From STAT: Request for comment on upcoming report on NIH research
>
> Hello --
>
> Forwarding the below since Senate is out of the office! Thanks.

---------- Forwarded message ---------
From: **Florko, Nicholas** <nicholas.florko@statnews.com>
Date: Fri, Jul 5, 2019 at 2:22 PM
Subject: From STAT: Request for comment on upcoming report on NIH research
To: <mylesr@mail.nih.gov>

Hi Renate --

I'm a reporter over at STAT. Nice to meet you. I'm writing up an embargoed report set to go out Tuesday from an advocacy group about NIH funding for a potential gene therapy.

I'd like to get NIH's take on both the estimate from the authors on the level of funding taxpayers have invested in the treatment, and the group's calls for there to be guardrails on the price for the drug. I know that's vague, but I wanted to ask before I share more details: Would you be able to honor the 6AM embargo if I share more details with you?

Thanks,
Nick

--
Nick Florko
Washington Correspondent
202-549-4576
@NicholasFlorko

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From: Pollard, Ricquita (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC946982E43F43CB925773EA52C40AFA-POLLARDRD]
Sent: 8/21/2018 5:03:12 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Chatterjee, Sabarni (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4520fc058d6457aac24b57685235b12-chatterjees]
Subject: FW: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665
Attachments: Response to KEI_comments on A-311-2018.docx; 2018-16058 FRN_A-311-2018.pdf

Hi Mark,

I am processing a Start-Up Exclusive License application (A-311-2018) from Midissia Therapeutics for a cancer immunotherapy. The *Federal Register* Notice for this application (attached) was posted on July 27th and the comment period according to the notice ended August 13th. I received an email from James Love and Manon Ress on August 13th (see below) with comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) addressing four topics: 1) No discrimination against US residents in pricing, 2) Reduce term of exclusivity when revenues are large, 3) Developing countries, and 4) Transparency.

Please see my proposed response in the attached WORD document. If you have any questions or concerns, please let me know.

Thanks,
Ricquita

Ricquita D. Pollard, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute
9609 Medical Center Drive, Rm 1-E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): (240) 276-5530
Direct Phone: (240) 276-5490
Fax: (240) 276-5503
pollardrd@mail.nih.gov

https://ttc.nci.nih.gov/index.php

Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents.

From: James Love <james.love@keionline.org>
Sent: Monday, August 13, 2018 11:48 PM
To: Pollard, Ricquita (NIH/NCI) [E] <ricquita.pollard@nih.gov>
Subject: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

August 13, 2018

Ricquita Pollard, Technology Transfer Manager,
NCI Technology Transfer Center,
Via Email: pollardrd@mail.nih.gov.

Re: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Dear Ricquita Pollard:

The following are comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT), on the proposed exclusive license for patents noticed in the Federal Register for a license to Midissia Therapeutics ("Midissia") located in San Francisco, California.

1. No discrimination against US residents in pricing

We ask that the NIH include language in the proposed exclusive license to ensure that the prices in the U.S. for any drug, vaccine, medical device or other health technology using the inventions are not higher than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.

We consider this a modest request to protect U.S. residents, who paid for the R&D that created the licensed inventions.

2. Reduce term of exclusivity when revenues are large

In addition to an external reference pricing test, we propose that the exclusivity of the license in the U.S. should be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks.

Given the modest cost of acquiring an NIH patented invention, the amount of money the developer needs in sales to justify additional investments in R&D is reduced, as compared to cases where a company developes or acquires the technology from non government sources.

This request is consistent with the statutory requirements of 35 USC 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

One possible implementation of revenue benchmarks is as follows: exclusivity will be reduced by one year for every $500 million in revenue equivalents, earned after the first $1 billion, where revenue equivalent is defined as global cumulative sales plus market entry rewards as well as government grants or tax credits, for the product or products using the invention. However, the NIH could choose different benchmarks, so long as the limits on exclusivity address the requirements of 35 USC 209, that the incentive is "not greater than reasonably necessary."

3. Developing countries

We are concerned that several NIH funded inventions are not accessible in developing countries, due to prices that are high and not affordable in markets where per capita incomes are significantly lower than the United States. For this reason, we ask the NIH to limit the exclusivity in the license to countries that have per capita incomes that are at least 30 percent of the United States.

We also ask the NIH to reach out to the Medicines Patent Pool (MPP), in order to enter into an agreement that gives the MPP an option to negotiate non-exclusive open licenses for the inventions in developing countries.

4. Transparency

The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 USC 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to market.

Sincerely,

James Love
Knowledge Ecology International

Manon Anne Ress
Union for Affordable Cancer Treatment

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

August 20, 2018

James Love
Scientific and Technical Advisor
Knowledge Ecology International

Manon Anne Ress
Union for Affordable Cancer Treatment

IN RE: Your Letter Dated August 13, 2018 in response to 83 FR 35663, Published July 27, 2018 *"Prospective Grant of Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy"*

Dear James Love and Manon Ress:

b5

Please let me know if you have any questions.

Sincerely,

Ricquita Pollard, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cancer Immunotherapy

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to Midissia Therapeutics (''Midissia'') located in San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before August 13, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Ricquita Pollard, Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240) 276–5530; Facsimile: (240) 276–5504; Email: *pollardrd@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/248,964 filed Oct. 30, 2015 for ''Compositions and Methods for the Treatment of HER2-Expressing Solid Tumor ''[HHS Ref. No. E–187–2015/0US–01];
2. International Patent Application No. PCT/US2016/059680 filed October 31, 2016 for ''Compositions and Methods for Treatment of HER2-Expressing Solid Tumor'' [HHS Reference No. E–187–2015/0–PCT–02];
3. Canadian National Stage Patent Application (*No. not yet assigned*), filed April 30, 2018 [HHS Ref. No. E–187–2015/0–CA–03];
4. Japanese National Stage Patent Application No. 2018–521518, filed April 30, 2018 [HHS Ref. No. E–187–2015/0–JP–04];
5. Australian National Stage Patent Application No. 2016343845, filed April 30, 2018 [HHS Ref. No. E–187–2015/0–AU–05];
6. European National Stage Patent Application. (*No. not yet assigned*), filed April 30, 2018 [HHS Ref. No. E–187–2015/0–EP–06];
7. U.S. National Stage Patent Application No. 15/771,932, filed April 30, 2018 [HHS Ref. No. E–187–2015/0–US–07];

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to ''development and commercialization of Ad-HER2 vaccines as a therapeutic against HER2-positive cancers as covered within the scope of the Licensed Patent Rights, excluding uses in combination with vectors/adjuvants, checkpoint inhibitors or other immune modulators.''

This technology describes a recombinant adenoviral vector that expresses the extracellular (EC) and transmembrane (TM) domains of the human HER2 protein and is designed to induce a polyclonal anti-tumor response. HER2 is a member of the epidermal growth factor family and is overexpressed in subsets of breast, ovarian, gastric, colorectal, pancreatic and endometrial cancers. This vaccine encodes for the entire EC and TM domains of human HER2neu and is specifically contained within a recombinant adenoviral vector that has the knob of Adenovirus 5 and substituted fiber of Adenovirus 35. The substitution of the knob of Adenovirus 35 whose receptor is CD46 allows for efficient and maximal transduction of human dendritic and hematopoietic cells.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 19, 2018.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2018–16058 Filed 7–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Intramural Continuing Umbrella of Research Experiences (iCURE) Application (National Cancer Institute)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Alison Lin, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240) 276–6177 or Email your request, including your address to: *linaj@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the

From: Surabian, Karen (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=604A0E2013504631921434A90B327010-SURABIANK_1]
Sent: 6/29/2018 3:44:09 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]; Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]; Sayyid, Fatima (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9e45041bdb43719f7113a5aae27057-sayyidf]; Soukas, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1f6020157ac47948c6e34166b78e433-soukasp]
Subject: Draft Email in response to FRN for review
Attachments: Draft Email Response 062818.docx

Hello Mark,

Thank you for discussing this with us on Wednesday. Please see the attached for your review.

Please let me know if OGC (Dale) would want to see this as well.

I am available Monday if you want to further discuss.

Thank you again.

Sincerely,

Karen

Karen T. Surabian
Licensing and Patenting Manager
CDC Team
Technology Transfer and Intellectual Property Office (TTIPO)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
5601 Fishers Lane, Rm. 2G48, MSC 9804
Rockville, MD 20892

Phone: 301-594-9719
Email: karen.surabian@nih.gov

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Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of NIAID by one of its representatives.

Dear Mr. Love,

b5

From: Fine, Amanda (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=61290B74AA9A44358954C45439FFDEB6-FINEAB]
Sent: 7/5/2019 8:01:31 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
Subject: FW: From STAT: Request for comment on upcoming report on NIH research
Attachments: Screen Shot 2019-07-05 at 3.08.38 PM.png

Hi Mark-

Please see below/attached. b5

b5

Amanda

From: Florko, Nicholas <nicholas.florko@statnews.com>
Sent: Friday, July 5, 2019 3:10 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: From STAT: Request for comment on upcoming report on NIH research

Appreciate you honoring the embargo. It's actually Patients For Affordable Drugs. And it's specifically about the sickle cell gene therapy LentiGlobin BB305. They say taxpayer-funded NIH research has invested more than $300 million into development of the therapy. (See table attached) Do you disagree with this number?

And then they're calling for NIH to impose guardrails on the pricing for the drug, including:
- a commitment from a drug manufacturer – upon acquiring the NIH-supported patent – to limit the U.S. price of a drug to no more than the average of comparable OECD nations.
- a commitment from a drug manufacturer that licensing agreements are contingent on the drug company agreeing to price the drug based on specific metrics. (Metrics could include: Manufacturing costs, royalty payments, clinical trials and R&D as reported to the IRS, and the value of tax credits received in exchange for the drug's development (i.e. orphan drug credits); Amount of money taxpayers invested in the drug; A profit margin based on the company's historic reported profit and loss over a recent five-year period.)

They also suggest creating an outside advisory committee to assist NIH in developing a methodology to determine reasonable prices.

Any chance you all could comment on whether NIH has the ability to impose such restrictions on pricing for these drugs?

My deadline is 2PM Monday.

Thank you!

On Fri, Jul 5, 2019 at 2:36 PM Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Hi Nick-
>
> Thanks for reaching out. Is it KEI? We can honor the embargo. What are your specific questions? We can look into them and do our best to get back to you by your deadline.
>
> Thanks,
> Amanda
>
> Get Outlook for iOS
>
> ---
>
> **From:** Florko, Nicholas <nicholas.florko@statnews.com>
> **Sent:** Friday, July 5, 2019 2:30:46 PM
> **To:** Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
> **Subject:** Fwd: From STAT: Request for comment on upcoming report on NIH research
>
> Hello --
>
> Forwarding the below since Senate is out of the office! Thanks.
>
> ---------- Forwarded message ---------
> From: **Florko, Nicholas** <nicholas.florko@statnews.com>
> Date: Fri, Jul 5, 2019 at 2:22 PM
> Subject: From STAT: Request for comment on upcoming report on NIH research
> To: <mylesr@mail.nih.gov>
>
> Hi Renate --

I'm a reporter over at STAT. Nice to meet you. I'm writing up an embargoed report set to go out Tuesday from an advocacy group about NIH funding for a potential gene therapy.

I'd like to get NIH's take on both the estimate from the authors on the level of funding taxpayers have invested in the treatment, and the group's calls for there to be guardrails on the price for the drug. I know that's vague, but I wanted to ask before I share more details: Would you be able to honor the 6AM embargo if I share more details with you?

Thanks,
Nick

--
Nick Florko
Washington Correspondent
202-549-4576
@NicholasFlorko

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--
Nick Florko
Washington Correspondent
202-549-4576
@NicholasFlorko

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--
Nick Florko
Washington Correspondent
202-549-4576
@NicholasFlorko

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b5

From: Fine, Amanda (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FINEAB]
Sent: 10/31/2016 2:58:37 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]; Chang, Kevin (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=RECIPIENTS/cn=CHANGKE]; Ano, Susan (NIH/NINDS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ANOS]; Rodriguez, Richard (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=RODRIQUR]; Niebylski, Charles (NIH/NIDDK) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Niebylskicd]
CC: Wojtowicz, Emma (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wojtowiczeme6d]; NCI Press Officers [/O=NIH/OU=NIHEXCHANGE/cn=NCI/cn=ncipressofficers]
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Thanks Mark! I've made the change. The background information has been cleared by HHS so will be sharing with Dan shortly.

Thanks again to all for your input.

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 31, 2016 10:46 AM
To: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Cc: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

b5

From: Myles, Renate (NIH/OD) [E]
Sent: Monday, October 31, 2016 10:16 AM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Cc: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Just a few more tweaks, including making Kevin's change.

From: Chang, Kevin (NIH/NCI) [E]
Sent: Monday, October 31, 2016 10:06 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>

Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

My only comment is that b5 b5

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 31, 2016 10:01 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Looks good. A couple edits...

From: Fine, Amanda (NIH/OD) [E]
Sent: Monday, October 31, 2016 9:52 AM
To: Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Good morning-

I know I sent the below draft background information late on Friday evening so just wanted to follow up this morning.

b5

b5

Thank you in advance for your guidance and input!
Amanda

From: Fine, Amanda (NIH/OD) [E]
Sent: Friday, October 28, 2016 6:11 PM
To: Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Sorry for the delay. For your review and input, please see the below draft response:

b5

b5

Thanks!

Amanda

On Oct 28, 2016, at 11:24 AM, Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov> wrote:

There's a typo in the email below. The first statement should read b5

b5

Best regards,

Sue

Susan Ano, Ph.D.
Technology Development Coordinator
Office of Technology Transfer
The National Institute of Neurological Disorders and Stroke

The National Institutes of Health
Mail address: 31 Center Drive, Suite 8A52, MS2540
Bethesda, MD 20892
Physical location: Bldg. 31, 8A07
phone (301) 435-5515
cell b6

<image001.jpg>

Have patience. All things are difficult before they become easy."
-- Saadi, poet

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:12 AM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

b5

Richard

From: Chang, Kevin (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:08 AM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Richard,

b5

Sue was working on responses to the questions.

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:04 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Amanda,

Just saw this and have attached my response to Chuck. If you have more questions, I'm happy to have a call.

Thanks,

Richard

RICHARD U. RODRIGUEZ, M.B.A.
Associate Director, Technology Transfer Center
Patent Agent

National Cancer Institute
National Institutes of Health
9609 Medical Center Drive, Rm 1E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): 240-276-5530
Direct phone: 240-276-6661
Fax 240-276-5504
richard.rodriguez@nih.gov

https://ttc.nci.nih.gov/index.php

"Change is inevitable. Progress is optional" – Tony Roberts

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From: Chang, Kevin (NIH/NCI) [E]
Sent: Thursday, October 27, 2016 6:26 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News
Importance: High

Hi Amanda,

Chuck has also approached me regarding these questions. Richard, Sue, and Mark may be the best positioned to provide NIH's official responses on these two questions. Richard should be back from travel on Monday but I can chat with Mark if he needs background about this specific license.

When do you need the responses to the questions by?

Best regards,

Kevin

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 5:03 PM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E]

<emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Kevin-

Please see the below long thread about a Buzzfeed inquiry regarding chlorcyclizine as a result of a complaint by Knowledge Ecology International. As you may know, KEI regularly approaches NIH regarding licensing and exercising march-in rights. We are working to set up an interview with Mark next week, however wanted to provide the reporter with some background. He asked a few questions about granting the license that folks said you would know and I was hoping you would help us in drafting responses to these questions. Specifically the following 2 questions:

2) What are the institute's priorities when licensing these drugs?

b5

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Please let me know if you have any questions.

Thank you in advance for your help and input!
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda.fine@nih.gov
Web: http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 3:42 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Just following up on this to see if there was any progress in drafting responses to Dan's questions. His deadline is tomorrow.

b5

b5

(2) What are the institute's priorities when licensing these drugs?

b5

(3) How much progress has this licensee made on marketing this drug?

You would need to check with the licensee.

(4) What were the results of the Phase 1 trial that NIH funded on this drug?

These will be published in the near future.

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Chuck-were you able to speak to Kevin Chang about this?

Thanks to all in advance for your input and guidance.

Best,
Amanda

b5

b5

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 11:34 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Morning Mark –

You had a bad address for Chuck so I'm adding him in with his NIDDK email.

This is actually for NIDDK to respond as we (OTT) would not feel comfortable answering questions for NIDDK on their licenses. That said, we will certainly assist NIDDK with the information we can find.

Chuck, let's chat on this tomorrow.
Deb

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 10:15 AM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov
Subject: Fwd: Interview request/chlorcyclizine pricing: BuzzFeed News

Deb and Karen:

Could you please help me follow up on this for Amanda and the press inquiry? b5

b5

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

From: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Date: October 24, 2016 at 9:49:59 PM GMT+1
To: "Niebylski, Charles (NIH/NIDDK) [E]" <niebylskicd@niddk.nih.gov>
Cc: "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Chuck:

See thread below. Could you help answer the questions about NIH licensing?

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

> **From:** "Portilla, Lili (NIH/NCATS) [E]" <portilll@mail.nih.gov>
> **Date:** October 24, 2016 at 9:22:01 PM GMT+1
> **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Vepa, Sury (NIH/NCATS) [E]" <sury.vepa@nih.gov>
> **Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News**
>
> Mark:
>
> NIDDK took the lead on this as their PI (Jake Liang) was the biology lead. NCATS has a few co-inventors on the patent who did screening and med chem. The licensing for this was done by OTT specifically Kevin Chang. Chuck Nybeliski was also very involved on the NCATS side when he was part of our office. I would speak to him on this matter in his role as Director of the NIDDK TTO.
>
> Regards,
>
> Lili
>
> *Lili M. Portilla, MPA*
> *Director, Office of Strategic Alliances*
> *National Center for Advancing Translational Sciences, NIH*
> *9800 Medical Center Drive, Room 3042*
> *Rockville, MD 20850*
> *Phone: 301-217-2589*

Email: Lilip@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:51 PM
To: Driscoll, Claire (NIH/NHGRI) [E] <cdriscol@mail.nih.gov>; Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Sorry Claire, meant to copy Lili

Sent from my iPhone

On Oct 24, 2016, at 8:50 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

> b5
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
> > **Date:** October 24, 2016 at 8:27:59 PM GMT+1
> > **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> > **Cc:** "McBurney, Margaret (NIH/OD) [E]" <mmcburney@od.nih.gov>, "Hardesty, Rebecca (NIH/OD) [C]"

<rebecca.hardesty@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>, "Wojtowicz, Emma (NIH/OD) [E]" <emma.wojtowicz@nih.gov>

Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

b5

Thanks Mark! Hope you're not working while on vacation.

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:22 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: McBurney, Margaret (NIH/OD) [E] <mmcburney@od.nih.gov>; Hardesty, Rebecca (NIH/OD) [C] <rebecca.hardesty@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

I am available. Looks ok to me. Not sure why the email thread was released under FOIA. There is more one could say but this is the basic message. b5

b5

Sent from my iPhone

On Oct 24, 2016, at 8:10 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

Greetings-

I’m including all three of you per Mark’s out of office and given that the reporter’s deadline is October 28.

NIDDK received the below inquiry from Dan Vergano at Buzzfeed regarding Knowledge Ecology International’s (KEI) questions about the drug chlorcyclizine which had/has a small trial at the CC.

Attached is a back and forth with NIDDK/NCATS that KEI got through FOIA. Dan’s questions are below.

b5

b5

b5

b5

Thank you in advance for your input and guidance,
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda.fine@nih.gov
Web: http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

From: Payne, January (NIH/NIDDK) [E]
Sent: Monday, October 24, 2016

2:54 PM
To: OCPLPressTeam <OCPLPressTeam@od.nih.gov>; ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Cc: NIDDK NIDDK MEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Interview request/chlorcyclizine pricing: BuzzFeed News

Hello, NIDDK received an interview request from a

Buzzfeed reporter asking about NIH involvement in licensing and drug pricing for chlorcyclizine. Chuck Niebylski, director of NIDDK’s Technology Advancement Office, asked that I refer this request to NIH OD as it involves NIH’s policy on drug pricing.

Below is the complete email exchange I’ve had with the reporter, Dan Vergano, and attached is a PDF of an email chain between NIH employ ees that the reporter received via a public interest group called Knowledge Ecology International, which obtained the records via a FOIA request. (Please note, for background: KEI also published this 2015 post about the same drug.)

Is NIH OD able to respond to this request?

Thank you,
January W. Payne
Office of Communications and Public Liaison
National Institute of

Diabetes and Digestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH
Direct 301-435-8115
Cell
b6
Office 301-496-3583
www.niddk.nih.gov
NIH...Turning Discovery Into Health®

Celebration of Science at NIH: *Watch how medical research saves lives and improves health*

From: Dan Vergan

o [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 12:29 PM
To: Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov>
Subject: Re: BuzzFeed News: press contact / licensing

January,

Thanks for getting back to me

-- The drug is chlorcyclizine (link to license annc't below), and the public interest group, Knowledge Ecology International (which often looks at NIH licenses) is complaining that its request for "reasonable pricing" requirements in the license were brushed aside to the detriment of taxpayers. The group has just received a public records request (a portion is attached) and suggests they show that NIH is worried more about scaring off the licensee than benefiting the taxpayers who funded this drug and have no assurance they won't have to pay excessively high prices for it.

-- I'm looking for an agency response to this contention.

-- My deadline is 10/28/16 at 5 PM EDT

-- My questions would basically be:
How do you respond to their complaint?
What are the institute's priorities when licensing these drugs?
How much progress has this licensee made on marketing this drug?
What were the results of the Phase 1 trial that NIH funded

on this drug? Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

I'd have follow-ups depending on the answers, natch, and would want to hear any responses to smarter questions on all this that your folks might have.

Any help appreciated,

Dan Vergano
BuzzFeed News
202 629 4563

Dan Vergano | Science Reporter (DC) | 202 629 4563
BuzzFeed 1630 Connecticut Ave. 7th Floor, Washington DC 20009

link: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-06974.pdf

Dan Vergano | Science Reporter (DC) | 202

629 4563
BuzzFeed
1630 Connecticut Ave. 7th Floor, Washington DC 20009

On Mon, Oct 24, 2016 at 11:57 AM, Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov> wrote:

> Dear Dan,
>
> Thanks for your message. Can you please provide more information so I

can look into your request?

- What is the drug name, and can you please briefly describe the issue that has been raised? Also, what is the name of the public interest group?

- What is your hard deadline?

- Can you please provide a few examples of questions you'd like to ask?

Best,

January W. Payne

Office of Communications and Public Liaison
National Institute of Diabetes and Digestive and Kidney Diseases

NATIONAL INSTITUTES OF HEALTH

www.niddk.nih.gov
NIH…Turning Discovery Into Health®

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Watch how medical research saves lives and improves health

From: Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 11:25 AM
To: NIDDK NIDDK MEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>

Subject: Fwd: BuzzFeed News: press contact / licensing

Krysten's email responder suggested I send this note to this contact. I have also left a phone message with the press office. I am looking for comment this week.

Ms. Carrera,

I'm a scienc

e reporter at BuzzFeed News. I'm looking for a press contact at NIDDK who can address a drug licensing issue at your institute. A public interest group is raising questions about one of your licenses and I'd like to get a response from the institute.

Thanks for any help,

Dan Vergano

BuzzFeed News

202/629-4563

Dan Vergano | Science Reporter (DC) | 202 629 4563 **BuzzFeed** 1630 Connecticut Ave. 7th Floor, Washington DC 20009

JANUARY PAYNE

@ National Institutes of Health

National Institutes of Health | 9000 Rockville Pike, Bethesda, MD 20892, USA | Official
(NIH). NIH is one of the world's foremost medical research centers. An agency of...

January Payne on LinkedIn

@NIH | 663K followers | 6K tweets - 3 hours ago

There's still time to submit your @NIH_LRP application! Get started on yours today.
#studentdebt

Search for January Payne on Google

Dan is using Senders. View / edit your own Card

<Reasonable Pricing - Virotas NIH.pdf>

<image001.jpg>

<image001.jpg>

<image001.jpg>

<image001.jpg>

From: Fine, Amanda (NIH/OD) [E]
To: Rohrbaugh, Mark (NIH/OD) [E]
Cc: Myles, Renate (NIH/OD) [E]
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News
Date: Wednesday, November 2, 2016 9:05:38 AM

Yes that is perfect! We can do the call from Renate's polycom.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, November 02, 2016 10:02 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Feeling better. Thx I will be coming in. Is 11:45 enough time? I could stop by

Sent from my iPhone

On Nov 2, 2016, at 9:55 AM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Hi Mark-
>
> Just checking in to see if you are (b) (6) and up for the call with Dan Vergano today.
>
> Renate and I were hoping to chat prior to your interview at noon so let us know when would be a good time to meet or give you a call. Dan gave us his number to call: (b) (6), however we can have him call you if you prefer just let me know what number I should provide him.
>
> Thank you again and hope you're feeling better!
> Amanda
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Tuesday, November 01, 2016 10:08 AM
> **To:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
> **Subject:** Re: Interview request/chlorcyclizine pricing: BuzzFeed News
>
> How about noon to 3?
>
> Sent from my iPhone
>
> On Nov 1, 2016, at 10:02 AM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:
>
>> Oh no I'm sorry to hear that! I'm sure we can arrange that. Is there a time I should offer? I will also let him know (b) (6).
>>
>> **From:** Rohrbaugh, Mark (NIH/OD) [E]
>> **Sent:** Tuesday, November 01, 2016 10:01 AM
>> **To:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
>> **Subject:** Re: Interview request/chlorcyclizine pricing: BuzzFeed News
>>
>> Today? (b) (6). Can we do it tomorrow?
>>
>> Sent from my iPhone

On Oct 31, 2016, at 1:59 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Hi Mark-
>
> Wasn't sure if you saw my below email. Is there a time tomorrow that would work for you to speak with Dan?
>
> Thanks again!
> Amanda
>
> ---
>
> **From:** Fine, Amanda (NIH/OD) [E]
> **Sent:** Monday, October 31, 2016 9:55 AM
> **To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> **Cc:** Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
> **Subject:** FW: Interview request/chlorcyclizine pricing: BuzzFeed News
>
> Good morning and welcome back!
>
> I wanted to check in to see what your availability is to speak to Dan either later today or sometime tomorrow. We're hoping to provide him with the background information prior to speaking with you.
>
> Thanks!
> Amanda
>
> ---
>
> **From:** Fine, Amanda (NIH/OD) [E]
> **Sent:** Friday, October 28, 2016 6:11 PM
> **To:** Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
> **Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
> **Subject:** Re: Interview request/chlorcyclizine pricing: BuzzFeed News
>
> Hi All-
>
> Sorry for the delay. For your review and input, please see the below draft response:
>
> (b) (5)
>
> [redacted]

[redacted] (b) (5)

Thanks!
Amanda

On Oct 28, 2016, at 11:24 AM, Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov> wrote:

There's a typo in the email below. The first statement should read [redacted] (b) (5) [redacted]

[redacted] (b) (5)

[redacted] (b) (5)

Best regards,

Sue

Susan Ano, Ph.D.
Technology Development Coordinator
Office of Technology Transfer
The National Institute of Neurological Disorders and Stroke
The National Institutes of Health
Mail address: 31 Center Drive, Suite 8A52, MS2540
Bethesda, MD 20892
Physical location: Bldg. 31, 8A07
phone (301) 435-5515
cell [redacted] (b) (6)

<image001.jpg>

Have patience. All things are difficult before they become easy."
-- Saadi, poet

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:12 AM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

[redacted] (b) (5)

[redacted] (b) (5)

Richard

From: Chang, Kevin (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:08 AM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Richard,

[redacted] (b) (5)

Sue was working on responses to the questions.

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:04 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz,

Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Amanda,

Just saw this and have attached my response to Chuck. If you have more questions, I'm happy to have a call.

Thanks,

Richard

RICHARD U. RODRIGUEZ, M.B.A.
Associate Director, Technology Transfer Center
Patent Agent

National Cancer Institute
National Institutes of Health
9609 Medical Center Drive, Rm 1E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): 240-276-5530
Direct phone: 240-276-6661
Fax 240-276-5504
richard.rodriguez@nih.gov

https://ttc.nci.nih.gov/index.php

"Change is inevitable. Progress is optional" – Tony Roberts

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From: Chang, Kevin (NIH/NCI) [E]
Sent: Thursday, October 27, 2016 6:26 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers

<ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News
Importance: High

Hi Amanda,

Chuck has also approached me regarding these questions. Richard, Sue, and Mark may be the best positioned to provide NIH's official responses on these two questions. Richard should (b) (6) on Monday but I can chat with Mark if he needs background about this specific license.

When do you need the responses to the questions by?

Best regards,

Kevin

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 5:03 PM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers

<nciipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Kevin-

Please see the below long thread about a Buzzfeed inquiry regarding chlorcyclizine as a result of a complaint by Knowledge Ecology International. As you may know, KEI regularly approaches NIH regarding licensing and exercising march-in rights. We are working to set up an interview with Mark next week, however wanted to provide the reporter with some background. He asked a few questions about granting the license that folks said you would know and I was hoping you would help us in drafting responses to these questions. Specifically the following 2 questions:

2) What are the institute's priorities when licensing these drugs?

(b) (5)

[redacted]

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Please let me know if you have any questions.

Thank you in advance for your help and input!
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda fine@nih.gov
Web: http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 3:42 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rohrbaugh, Mark (NIH/OD)

[E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD)
[E] <RogersK@od.nih.gov>
Cc: charles.nybeliski@nih.gov; Niebylski, Charles
(NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing:
BuzzFeed News

Hi All-

Just following up on this to see if there was any progress in drafting responses to Dan's questions. His deadline is tomorrow.

As I mentioned before, [redacted] (b) (5)

[redacted] (b) (5)

(2) What are the institute's priorities when licensing these drugs?

[redacted] (b) (5)

[redacted] (b) (5)

(3) How much progress has this licensee made on marketing this drug?

You would need to check with the licensee.

(4) What were the results of the Phase 1 trial that NIH funded on this drug?

These will be published in the near future.

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Chuck-were you able to speak to Kevin Chang about this?

Thanks to all in advance for your input and guidance.

Best,
Amanda

[redacted] (b) (5)

(b) (5)

[redacted]

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 11:34 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Morning Mark –

You had a bad address for Chuck so I'm adding him in with his NIDDK email.

This is actually for NIDDK to respond as we (OTT) would not feel comfortable answering questions for NIDDK on their licenses. That said, we will certainly assist NIDDK with the information we can find.

Chuck, let's chat on this tomorrow.
Deb

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 10:15 AM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov
Subject: Fwd: Interview request/chlorcyclizine pricing: BuzzFeed News

Deb and Karen:

Could you please help me follow up on this for Amanda and the press inquiry? [redacted] (b) (5)

(b) (5)

[redacted]

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

> **From:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Date:** October 24, 2016 at 9:49:59 PM GMT+1
> **To:** "Niebylski, Charles (NIH/NIDDK) [E]" <niebylskicd@niddk.nih.gov>
> **Cc:** "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
> **Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News**
>
> > Chuck:
> >
> > See thread below. Could you help answer the questions about NIH licensing?
> >
> > Thanks
> > Mark
> >
> > Sent from my iPhone
> >
> > Begin forwarded message:
> >
> > > **From:** "Portilla, Lili (NIH/NCATS) [E]" <portilll@mail.nih.gov>
> > > **Date:** October 24, 2016 at 9:22:01 PM GMT+1
> > > **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Vepa, Sury (NIH/NCATS) [E]" <sury.vepa@nih.gov>
> > > **Subject: RE: Interview**

request/chlorcyclizine pricing: BuzzFeed News

Mark:

NIDDK took the lead on this as their PI (Jake Liang) was the biology lead. NCATS has a few co-inventors on the patent who did screening and med chem. The licensing for this was done by OTT specifically Kevin Chang. Chuck Nybeliski was also very involved on the NCATS side when he was part of our office. I would speak to him on this matter in his role as Director of the NIDDK TTO.

Regards,

Lili

Lili M. Portilla, MPA
Director, Office of Strategic Alliances
National Center for Advancing Translational Sciences, NIH
9800 Medical Center Drive, Room 3042
Rockville, MD 20850
Phone: 301-217-2589
Email:

Lilip@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:51 PM
To: Driscoll, Claire (NIH/NHGRI) [E] <cdriscol@mail.nih.gov>; Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Sorry Claire, meant to copy Lili

Sent from my iPhone

On Oct 24, 2016, at 8:50 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

(b) (5)

[redacted] (b) (5)

Sent from my iPhone

Begin forwarded message:

From: "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
Date: October 24, 2016 at 8:27:59 PM GMT+1
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: "McBurney, Margaret (NIH/OD) [E]" <mmcburney@od.nih.gov>, "Hardesty, Rebecca (NIH/OD) [C]" <rebecca.hardesty@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>,

"Wojtowicz, Emma (NIH/OD) [E]" <emma.wojtowicz@nih.gov>

Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

(b) (5)

[redacted]

(b) (5)

(b) (5)

[redacted]

Thanks Mark! Hope you're not working while on vacation.

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:22 PM
To: Fine, Amanda (NIH/OD) [E]

<amanda.fine@nih.gov>
Cc: McBurney, Margaret (NIH/OD) [E] <mmcburney@od.nih.gov>; Hardesty, Rebecca (NIH/OD) [C] <rebecca.hardesty@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

I am available. Looks ok to me. Not sure why the email thread was released under FOIA.

There is more one could

say but this is the basic message.

(b) (5)

[redacted]

Sent from my iPhone

On Oct 24, 2016, at 8:10 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

Greetings-

I’m including all three of you per Mark’s out of office and given that the reporter’s deadline is October 28.

NIDDK received the below inquiry from Dan Vergano at Buzzfeed regarding Knowledge Ecology International’s (KEI) questions about the drug chlorcyclizine which had/has a small trial at the CC. Attached is a back and forth with NIDDK/NCATS that KEI got through FOIA. Dan’s questions are below.

(b) (5)

[redacted]

(b) (5)

(b) (5)

[redacted]

(b) (5)

Thank you in advance for your input and guidance,
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda fine@nih.gov
Web: http://www nih.gov

NIH . . . *Turning Discovery Into Health*

From: Payne, January (NIH/NIDDK) [E]
Sent: Monday, October 24, 2016 2:54 PM
To: OCPLPressTeam <OCPLPressTeam@od.nih.gov>;

ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Cc: NIDDK NIDDKMEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Interview request/chlorcyclizine pricing: BuzzFeed News

Hello, NIDDK received an interview request from a Buzzfeed reporter asking about NIH involvement in licensing and drug pricing for chlorcyclizine. Chuck Niebylski, director of NIDDK’s Technology Advancement Office, asked that I refer this request to NIH OD as it involves

NIH’s policy on drug pricing.

Below is the complete email exchange I’ve had with the reporter, Dan Vergano, and attached is a PDF of an email chain between NIH employees that the reporter received via a public interest group called Knowledge Ecology International, which obtained the records via a FOIA request. (Please note, for background: KEI also published this 2015 post about the same drug.)

Is NIH OD able to respond to this request?

Thank you,
January W. Payne
Office of Communications and Public Liaison
National Institute of Diabetes and Digestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH
Direct 301-435-8115
Cell (b) (6)
Office 301-496-3583
www.niddk.nih.gov

NIH...Turning Discovery Into Health®

Celebration of Science

at NIH: *Watch how medical research saves lives and improves health*

From: Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 12:29 PM
To: Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov>
Subject: Re: BuzzFeed News: press contact / licensing

January,

Thanks for getting back to me

-

- The drug is chlorcyclizine

(link to license annc't below), and the public interest group, Knowledge Ecology International (which often looks at NIH licenses) is complaining that its request for "reasonable pricing" requirements in the license were brushed aside to the detriment of taxpayers. The group has just received a public records request (a portion is attached) and suggests they show that NIH is worried more about scaring off the licensee than benefiting the taxpayers who funded this drug and have no assurance they won't have to pay excessively high prices for it.

- - I'm looking for an agency response to this contention.

- - My deadline is 10/28/16 at 5 PM EDT

- - My questions would basically be: How do you respond to their complaint? What are the institute's priorities when licensing these drugs? How much progress has this licensee made on marketing this drug? What were the results of the Phase 1 trial that NIH funded on this drug? Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

I'd have follow-ups depending on the answers, natch, and would want to hear any responses to smarter questions on all this that your folks might have.

Any help appreciated,

Dan Vergano
BuzzFeed News
202 629 4563

Dan Vergano | Science Reporter (DC) | 202 629 4563

BuzzFeed

1630 Connecticut Ave. 7th Floor, Washington DC 20009

link: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-06974.pdf

Dan Vergano | Science Reporter (DC) | 202 629 4563

BuzzFeed

1630 Connecticut Ave. 7th Floor, Washington DC 20009

On Mon, Oct 24, 2016 at 11:57 AM, Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov> wrote:

> Dear Dan,
>
> Thanks for your message. Can you please provide more

information so I can look into your request?

- What is the drug name, and can you please briefly describe the issue that has been raised? Also, what is the name of the public interest group?

- What is your hard deadline?

- Can you please provide a few

examples of questions you’d like to ask?

Best,
January W. Payne
Office of Communications and Public Liaison
National Institute of Diabetes and Digestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH
www.niddk.nih.gov
NIH...Turning Discovery Into Health®

Celebration of Science at NIH: *Watch how medical research saves lives and improves health*

From:

Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 11:25 AM
To: NIDDK NIDDKMEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Fwd: BuzzFeed News: press contact / licensing

Krysten's email responder suggested I send this note to this contact. I have also left a phone message with the press office. I am looking for comment this week.

Ms. Carrera,

I'm a science reporter at BuzzFeed News. I'm looking for a press contact at NIDDK who can address a drug licensing issue at your institute. A public interest group is raising questions about one of your licenses and I'd like to get a response from the institute.

Thanks for any help,

Dan

Vergano
BuzzFeed
News
202/629-4563

Dan Vergano | Science Reporter (DC) | 202 629 4563

BuzzFeed

1630 Connecticut Ave. 7th Floor, Washington DC 20009

JANUARY PAYNE Senders Card ☐

@ National Institutes of Health

National Institutes of Health | 9000 Rockville Pike, Bethesda, MD 20892, USA | Official website of the National Institutes of Health (NIH). NIH is one of the world's foremost medical research centers. An agency of...

January Payne on LinkedIn

@NIH | 663K followers |

6K tweets - 3 hours ago

There's still time to submit your @NIH_LRP application! Get started on yours today. Deadline is Nov.15 bit.ly/2e7QDzt #studentdebt

Search for January Payne on Google

Dan is using Senders. View / edit your own Card

<Reasonable Pricing - Virotas NIH.pdf>

<image001.jpg>

<image001.jpg>

<image001.jpg>

<image001.jpg>

From: Fine, Amanda (NIH/OD) [E]
To: Rohrbaugh, Mark (NIH/OD) [E]
Cc: Myles, Renate (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News
Date: Tuesday, November 1, 2016 10:07:16 AM

Hi Mark-

Dan confirmed tomorrow at 12pm to speak with you.

Thanks!
Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, November 01, 2016 10:08 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

How about noon to 3?

Sent from my iPhone

On Nov 1, 2016, at 10:02 AM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Oh no I'm sorry to hear that! I'm sure we can arrange that. Is there a time I should offer? I will also let him know [redacted] (b) (6)
>
> ---
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Tuesday, November 01, 2016 10:01 AM
> **To:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
> **Subject:** Re: Interview request/chlorcyclizine pricing: BuzzFeed News
>
> Today? [redacted] (b) (6). Can we do it tomorrow?
>
> Sent from my iPhone
>
> On Oct 31, 2016, at 1:59 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:
>
>> Hi Mark-
>>
>> Wasn't sure if you saw my below email. Is there a time tomorrow that would work for you to speak with Dan?
>>
>> Thanks again!
>> Amanda
>>
>> ---
>>
>> **From:** Fine, Amanda (NIH/OD) [E]
>> **Sent:** Monday, October 31, 2016 9:55 AM
>> **To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>

Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: FW: Interview request/chlorcyclizine pricing: BuzzFeed News

Good morning and welcome back!

I wanted to check in to see what your availability is to speak to Dan either later today or sometime tomorrow. We're hoping to provide him with the background information prior to speaking with you.

Thanks!
Amanda

From: Fine, Amanda (NIH/OD) [E]
Sent: Friday, October 28, 2016 6:11 PM
To: Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Sorry for the delay. For your review and input, please see the below draft response:

(b) (5)

[redacted]

(b) (5)

[redacted]

Thanks!
Amanda

On Oct 28, 2016, at 11:24 AM, Ano, Susan (NIH/NINDS) [E]
<susan.ano@nih.gov> wrote:

There's a typo in the email below. The first statement should read [redacted] (b) (5)

(b) (5)

[redacted]

Best regards,

Sue

Susan Ano, Ph.D.
Technology Development Coordinator
Office of Technology Transfer
The National Institute of Neurological Disorders and Stroke

The National Institutes of Health
Mail address: 31 Center Drive, Suite 8A52, MS2540
Bethesda, MD 20892
Physical location: Bldg. 31, 8A07
phone (301) 435-5515
cell [redacted] (b) (6)

<image001.jpg>

Have patience. All things are difficult before they become easy."
-- Saadi, poet

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:12 AM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

(b) (5)

[redacted]

Richard

From: Chang, Kevin (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:08 AM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E]

<susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Richard,

(b) (5)
[redacted]

Sue was working on responses to the questions.

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Rodriguez, Richard (NIH/NCI) [E]
Sent: Friday, October 28, 2016 11:04 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Amanda,

Just saw this and have attached my response to Chuck. If you have more questions, I'm happy to have a call.

Thanks,

Richard

RICHARD U. RODRIGUEZ, M.B.A.
Associate Director, Technology Transfer Center
Patent Agent

National Cancer Institute
National Institutes of Health
9609 Medical Center Drive, Rm 1E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): 240-276-5530
Direct phone: 240-276-6661
Fax 240-276-5504
richard.rodriguez@nih.gov

https://ttc.nci.nih.gov/index.php

"Change is inevitable. Progress is optional" – Tony Roberts

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From: Chang, Kevin (NIH/NCI) [E]
Sent: Thursday, October 27, 2016 6:26 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Ano, Susan (NIH/NINDS) [E] <susan.ano@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News
Importance: High

Hi Amanda,

Chuck has also approached me regarding these questions. Richard, Sue, and Mark may be the best positioned to provide

NIH's official responses on these two questions. Richard should (b) (6) on Monday but I can chat with Mark if he needs background about this specific license.

When do you need the responses to the questions by?

Best regards,

Kevin

Kevin W. Chang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
9609 Medical Center Dr.
Room 3W-128, MSC 9702
Rockville, MD 20850-9702
Phone: 240-276-6910
Email: changke@mail.nih.gov

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From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 5:03 PM
To: Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; NCI Press Officers <ncipressofficers@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi Kevin-

Please see the below long thread about a Buzzfeed inquiry regarding chlorcyclizine as a result of a complaint by Knowledge Ecology International. As you may know, KEI regularly approaches NIH regarding licensing and exercising march-in rights. We are working to set up an interview with Mark next week, however wanted to provide the reporter with some background. He asked a few questions about granting the license that folks said you would know and I was hoping you would help us in drafting responses to these questions. Specifically the following 2 questions:

2) What are the institute's priorities when licensing these drugs?

(b) (5)
[redacted]

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Please let me know if you have any questions.

Thank you in advance for your help and input!
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda fine@nih.gov
Web: http://www nih.gov

NIH . . . *Turning Discovery Into Health*

From: Fine, Amanda (NIH/OD) [E]
Sent: Thursday, October 27, 2016 3:42 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E] <niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Hi All-

Just following up on this to see if there was any progress in drafting responses to Dan's questions. His deadline is tomorrow.

As I mentioned before, [redacted] (b) (5)
(b) (5)
[redacted]

[redacted] (b) (5)

(2) What are the institute's priorities when licensing these drugs?

[redacted] (b) (5)

(3) How much progress has this licensee made on marketing this drug?

You would need to check with the licensee.

(4) What were the results of the Phase 1 trial that NIH funded on this drug?

These will be published in the near future.

(5) Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Chuck-were you able to speak to Kevin Chang about this?

Thanks to all in advance for your input and guidance.

Best,
Amanda

[redacted]

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 11:34 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>;

charles.nybeliski@nih.gov; Niebylski, Charles (NIH/NIDDK) [E]
<niebylskicd@niddk.nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

Morning Mark –

You had a bad address for Chuck so I'm adding him in with his NIDDK email.

This is actually for NIDDK to respond as we (OTT) would not feel comfortable answering questions for NIDDK on their licenses. That said, we will certainly assist NIDDK with the information we can find.

Chuck, let's chat on this tomorrow.
Deb

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 25, 2016 10:15 AM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; charles.nybeliski@nih.gov
Subject: Fwd: Interview request/chlorcyclizine pricing: BuzzFeed News

Deb and Karen:

Could you please help me follow up on this for Amanda and the press inquiry? [redacted] (b) (5)

[redacted] (b) (5)

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

> **From:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
> **Date:** October 24, 2016 at 9:49:59 PM GMT+1
> **To:** "Niebylski, Charles (NIH/NIDDK) [E]" <niebylskicd@niddk.nih.gov>
> **Cc:** "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>

Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Chuck:

See thread below. Could you help answer the questions about NIH licensing?

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

> **From:** "Portilla, Lili (NIH/NCATS) [E]" <portilll@mail.nih.gov>
> **Date:** October 24, 2016 at 9:22:01 PM GMT+1
> **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Vepa, Sury (NIH/NCATS) [E]" <sury.vepa@nih.gov>
> **Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News**
>
> Mark:
>
> NIDDK took the lead on this as their PI (Jake Liang) was the biology lead. NCATS has a few co-inventors on the patent who did screening and med chem. The licensing for this was done by OTT specifically Kevin Chang. Chuck Nybeliski was also very involved on the NCATS side when he was part of our office. I

would speak to him on this matter in his role as Director of the NIDDK TTO.

Regards,

Lili

Lili M. Portilla, MPA
Director, Office of Strategic Alliances
National Center for Advancing Translational Sciences, NIH
9800 Medical Center Drive, Room 3042
Rockville, MD 20850
Phone: 301-217-2589
Email: Lilip@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:51 PM
To: Driscoll, Claire (NIH/NHGRI) [E] <cdriscol@mail.nih.gov>; Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

Sorry Claire, meant to copy Lili

Sent from my iPhone

On Oct 24, 2016, at 8:50 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

> (b) (5)
>
> [redacted]
>
> Sent from my iPhone
>
> Begin forwarded message:
>
>> **From:** "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
>> **Date:** October 24, 2016 at 8:27:59 PM GMT+1
>> **To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
>> **Cc:** "McBurney, Margaret (NIH/OD) [E]"

<mmcburney@od.nih.gov>,
"Hardesty,
Rebecca
(NIH/OD)
[C]"
<rebecca.hardesty@nih.gov>,
"Myles,
Renate
(NIH/OD)
[E]"
<mylesr@od.nih.gov>,
"Wojtowicz,
Emma
(NIH/OD)
[E]"
<emma.wojtowicz@nih.gov>

Subject:
RE:
Interview
request/chlorcyclizine
pricing:
BuzzFeed
News

(b) (5)

[redacted]

(b) (5)

[redacted]

(b) (5)

[redacted]

Thanks Mark! Hope you're not working while on vacation.

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:22 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: McBurney, Margaret (NIH/OD) [E] <mmcburney@od.nih.gov>; Hardesty, Rebecca (NIH/OD) [C] <rebecca.hardesty@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

I am available. Looks ok to me. Not sure why the email thread was released under FOIA.

There is more one could say but this is the basic message.

(b) (5)

[redacted]

(b) (5)

Sent from my iPhone

On Oct 24, 2016, at 8:10 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

> Greetings-
>
> I'm including all three of you per Mark's out of office and given that the reporter's deadline is October 28.
>
> NIDDK received the below

inquiry from Dan Vergano at Buzzfeed regarding Knowledge Ecology International's (KEI) questions about the drug chlorcyclizine which had/has a small trial at the CC. Attached is a back and forth with NIDDK/NCATS that KEI got through FOIA. Dan's questions are below.

(b) (5)

[redacted]

(b) (5)

[redacted]

(b) (5)

[redacted]

(b) (5)

Thank you in advance for your input and guidance,

Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda fine@nih.gov
Web: http://www nih.gov

NIH . . . *Turning Discovery Into Health*

From: Payne, January (NIH/NIDDK) [E]
Sent: Monday, October 24, 2016 2:54 PM
To: OCPLPressTeam <OCPLPressTeam@od.nih.gov>; ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Cc: NIDDK NIDDKMEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>

Subject: Interview request/chlorcyclizine pricing: BuzzFeed News

Hello,
NIDDK received an interview request from a Buzzfeed reporter asking about NIH involvement in licensing and drug pricing for chlorcyclizine. Chuck Niebylski, director of NIDDK's Technology Advancement Office, asked that I refer this request to NIH OD as it involves NIH's policy on drug pricing.

Below is the complete

email exchange I’ve had with the reporter, Dan Vergano, and attached is a PDF of an email chain between NIH employees that the reporter received via a public interest group called Knowledge Ecology International, which obtained the records via a FOIA request. (Please note, for background: KEI also published this 2015 post about the same drug.)

Is NIH OD

able to respond to this request?

Thank you,

January W. Payne
Office of Communications and Public Liaison
National Institute of Diabetes and Digestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH
Direct 301-435-8115
Cell (b) (6)
Office 301-496-3583
www.niddk.nih.gov

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From: Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 12:29 PM
To: Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov>
Subject: Re: BuzzFeed News: press contact / licensing

January,

Thanks for getting back to me

-
-
The drug is

chlorcyclizine (link to license annc't below), and the public interest group, Knowledge Ecology International (which often looks at NIH licenses) is complaining that its request for "reasonable pricing" requirements in the license were brushed aside to the detriment of taxpayers. The group has just received a public records request (a portion is attached) and suggests they show that NIH is worried more about scaring off the licensee than benefiting the taxpayers who funded this drug and have no assurance they won't have to pay excessively high prices for it.

- - I'm looking for an agency response to this contention.

- - My deadline is 10/28/16 at 5 PM EDT

- - My questions would basically be:

How do you respond to their complaint? What are the institute's priorities when licensing these drugs? How much progress has this licensee made on marketing this drug? What were the results of the Phase 1 trial that NIH funded on this drug? Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

I'd have follow-ups depending on the answers, natch, and would want to hear any responses to smarter questions on all this that your folks might have.

Any help appreciated,

Dan Vergano
BuzzFeed News
202 629 4563

Dan Vergano | Science Reporter (DC)

|
202
629
4563

BuzzFeed

1630
Connecticut
Ave.
7th
Floor,
Washington
DC
20009

link:
https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-06974.pdf

**Dan
Vergano**
|
Science
Reporter
(DC)
|
202
629
4563

BuzzFeed

1630
Connecticut
Ave.
7th
Floor,
Washington
DC
20009

On
Mon,
Oct
24,
2016
at
11:57
AM,
Payne,
January

(NIH/NIDDK) [E] <january.payne@nih.gov> wrote:

> Dear Dan,
>
> Thanks for your message. Can you please provide more information so I can look into your request?
>
> - What is the drug name, and can you please briefly describe the issue that has been raised? Also, what is the name

of the public interest group?

- What is your hard deadline?

- Can you please provide a few examples of questions you'd like to ask?

Best,

January
W.
Payne
Office
of
Communications
and
Public
Liaison
National
Institute
of
Diabetes
and
Digestive
and
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From: Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 11:25 AM
To: NIDDK NIDDKMEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Fwd: BuzzFeed News: press contact / licensing

Krysten's

email responder suggested I send this note to this contact. I have also left a phone message with the press office. I am looking for comment this week.

Ms. Carrera,

I'm a science reporter at BuzzFeed News. I'm looking for a press contact at NIDDK who can address a drug licensing issue at your institute. A public interest group is raising questions about one of your licenses and I'd like to get a response from the institute.

Thanks for any help,

Dan Vergano
BuzzFeed News
202/629-4563

Dan Vergano | Science Reporter (DC) | 202 629 4563

BuzzFeed

1630 Connecticut

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7th
Floor,
Washington
DC
20009

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January Payne on LinkedIn

@NIH | 663K followers | 6K tweets - 3 hours ago

There's still time to submit your @NIH_LRP application! Get started on yours today. Deadline is Nov.15 bit.ly/2e7QDzt #studentdebt

Search for January Payne on Google

Dan is using

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<Reasonable Pricing - Virotas NIH .pdf>

<image001.jpg>

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